(i) subparagraph (1)(v) of 40 CFR § 93.105(c) is deleted; and

(ii) the reference in subparagraph (5) of 40 CFR § 93.105(c) to 40 CFR § 93.130 shall be deemed to refer to subparagraph (b)(4) of this regulation. (Authorized by and implementing K.S.A. 1995 Supp. 65-3005; effective March 15, 1996.)

Article 20.—HUMAN BODIES; PREPARATION AND TRANSPORTATION OF DEAD HUMAN BODIES AND BURIAL IN MAUSOLEUM

28-20-1. (Authorized by K.S.A. 65-102, 65-1638, 65-1639; effective Jan. 1, 1966; amended Jan. 1, 1969; revoked May 1, 1981.)

28-20-2. (Authorized by K.S.A. 65-102, K.S.A. 1968 Supp. 65-128; effective Jan. 1, 1966; revoked Jan. 1, 1969.)

28-20-2a. (Authorized by K.S.A. 65-102, 65-128; effective Jan. 1, 1969; revoked May 1, 1981.)

28-20-3. (Authorized by K.S.A. 65-102; effective Jan. 1, 1966; revoked Jan. 1, 1969.)

28-20-3a. (Authorized by K.S.A. 65-101, 65-102, 65-128, 65-2426; effective Jan. 1, 1969; amended Jan. 1, 1972; amended May 1, 1976; revoked May 1, 1981.)

28-20-4. (Authorized by K.S.A. 65-101, 65-102, 65-128; effective Jan. 1, 1966; amended Jan. 1, 1969; amended May 1, 1976; revoked May 1, 1981.)

28-20-5. (Authorized by K.S.A. 65-102, 65-128; effective Jan. 1, 1966; amended Jan. 1, 1969; revoked May 1, 1981.)

28-20-6. (Authorized by K.S.A. 65-102; effective Jan. 1, 1966; revoked May 1, 1981.)

28-20-7. (Authorized by K.S.A. 65-102, 65-128; effective Jan. 1, 1966; amended Jan. 1, 1969; revoked May 1, 1981.)

28-20-8. (Authorized by K.S.A. 65-102; effective Jan. 1, 1966; revoked May 1, 1981.)

Article 21.—FOOD, DRUGS AND COSMETICS

A. GENERAL REGULATIONS

28-21-1. Labeling; definition. Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is for sale, delivery, held for sale, or offered for sale in the state of Kansas. (Authorized by K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-2. Difference of opinion among experts. The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation. (Authorized by K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-3. (Authorized by K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966; revoked May 10, 1996.)

28-21-4. Guaranty; definition, and suggested forms. (a) A guaranty or undertaking referred to in K.S.A. 65-659 (b) may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or

(2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under K.S.A. 65-659 (b):

(1) Limited form for use on invoice or bill of sale:

(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Kansas food, drug and cosmetic act.

(Signature and post-office address of person giving the guaranty or undertaking.)

(2) General and continuing form:

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or on the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Kansas food, drug and cosmetic act.

(Signature and post-office address of person giving the guaranty or undertaking.)

(c) The application of a guaranty or undertaking referred to in K.S.A. 65-659 (b) to any ship-

ment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the act.

(d) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(e) No representation or suggestion that an article is guaranteed under the act shall be made in labeling. (Authorized by K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-5. Food; labeling; misbranding. (a) Among representations in a labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling. (Authorized by K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-6. Food; labeling; required statements; when exempt. (a) Where a food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such food, such as "manufactured for and packed by _____," "distributed by _____," or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) If a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such food was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any food from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents shall reveal the quantity of food in the package, exclusive of wrappers and other material packed with such food.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such food and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such food exists, the statement shall be in terms of liquid measure if the food is liquid, or in terms of weight if the food is solid, semi-solid, viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity.

(f) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof and except in case of frozen food which is so consumed, shall express the volume at 68° Fahrenheit (20° centigrade). A statement of dry measure shall be in terms of the United States bushel of 2150.42 cubic inches and peck, dry quart, and dry pint subdivisions thereof; or in terms of the United States standard barrel and its subdivisions of third, half, and three-quarters barrel. However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which such shipment is exported.

(2) A statement of weight or measure in the terms specified in subparagraph (1) of this paragraph may be supplemented by a statement in terms of the metric system of weight or measure.

(3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of food in the package, it shall be supplemented by such statement of weight, measure, or size of the individual units of the food as will give such information.

(g) Statements shall contain only such fractions as are generally used in expressing the quantity of the food. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(h) (1) If the quantity of food in the package equals or exceeds the smallest unit of weight or

measure which is specified in paragraph (f) of this section, and which is applicable to such food under the provisions of paragraph (e) (2) of this section, the statement shall express the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one quart of food shall be "1 quart," and not "2 pints" or "32 fluid ounces"), unless the statement is made in accordance with the provisions of subparagraph (2) of this paragraph. Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for example, 1¾ quarts may be expressed as "1 quart 1½ pints" or "1 quart 1 pint 8 fluid ounces"; 1¼ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in such paragraph (f)) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for examples, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint"; instead of "24 ounces" the statement shall be "1½ pounds" or "1 pound 8 ounces").

(2) In the case of a food with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to express the average quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the food is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(k) Where the statement does not express the minimum quantity:

(1) Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) Variations from the stated weight, measure, or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting individual packages which occur in good packing practice.

But under subparagraph (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the food is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A food shall be exempt from compliance with the requirements of clause (2) of K.S.A. 65-665 (e) if:

(1) The quantity of the contents, as expressed in terms applicable to such food under the provisions of paragraph (e) (2) of this section, is less than one-half ounce avoirdupois, or less than one-half fluid ounce, or (in case the units of the food can be easily counted without opening the package) less than six units; or

(2) The statement of the quantity of the contents of the package, together with all other words, statements, and information required by or under authority of the act to appear on the label, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of K.S.A. 65-665 (f) and regulations promulgated thereunder.

(n) A food shall be exempt while held for sale from the requirements of clause (2) of K.S.A. 65-665 (e) (requiring a statement on the label of the quantity of contents) if said food, having been received in bulk containers at a retail establishment, is accurately weighed, measured, or counted either within the view of the purchaser or in compliance with the purchaser's order.

(o) A carbonated beverage sold under a dis-

tinctive name, may be exempt from the provisions of K.S.A. 65-665 (i) (2) if the parent firm, licensee or franchise owner shall file with the board of health a list of ingredients used in the carbonated beverage, except that spice, flavoring, or coloring may be designated as spice, flavoring, or coloring without naming each. (Authorized by K.S.A. 65-665 (e), K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-7. Food; labeling; prominence of required statements. (a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by K.S.A. 65-665 (f) by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under K.S.A. 65-665 (e) or (i) shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space, to give greater conspicuousness to any word, statement, or other information than is required by K.S.A. 65-665 (f); or

(3) The use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language. (Authorized by K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-8. Conformity to definitions and standards of identity. In the conditions, among others, a food does not conform to the definition and standard of identity therefor:

(a) If it contains an ingredient for which no provision is made in such definition and standard;

(b) If it fails to contain any one or more ingredients required by such definition and standard;

(c) If the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed therefor by such definition and standard. (Authorized by K.S.A. 65-663, K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-9. Food; labeling; designation of ingredients. (a) The name of an ingredient (except a spice, flavoring, or coloring which is an ingredient of a food other than one sold as a spice, flavoring, or coloring), required by K.S.A. 65-665 (i) (2) to be borne on the label of a food, shall be a specific name and not a collective name. But if an ingredient (which itself contains two or more ingredients) conforms to a definition and standard of identity prescribed by regulations under K.S.A. 65-663, such ingredient may be designated on the label of such food by the name specified in the definition and standard, supplemented, in case

such regulations require the naming of optional ingredients present in such ingredient, by a statement showing the optional ingredients which are present in such ingredient.

(b) No ingredient shall be designated on the label as a spice, flavoring, or coloring unless it is a spice, flavoring, or coloring, as the case may be, within the meaning of such term as commonly understood by consumers. The term "coloring" shall not include any bleaching substance.

(c) An ingredient which is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as spice and coloring, or flavoring and coloring, as the case may be, unless such ingredient is designated by its specific name.

(d) A label may be misleading by reason (among other reasons) of:

(1) The order in which the name of ingredients appear thereon, or the relative prominence otherwise given such names; or

(2) Its failure to reveal the proportion of, or other fact with respect to, an ingredient, when such proportion or other fact is material in the light of the representation that such ingredient was used in fabricating the food.

(e) (1) A food shall be exempt from the requirements of K.S.A. 65-665 (i) (2) if all words, statements, and other information required by or under authority of the act to appear on the label of such food, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of K.S.A. 65-665 (f) and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by such clause (2), such statement of the quantity of the contents shall be omitted as authorized by 28-21-6 (m) (2), and the information required by such clause (2) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(2) In the case of an assortment of different items of food, when variations in the items which make up different packages packed from such assortment normally occur in good packing practice, and when such variations result in variations in the ingredients in different packages, such food shall be exempt from compliance with the requirements of clause (2) of K.S.A. 65-665 (i) with respect to any ingredient which is not common to all packages. But such exemption shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement in terms which are as practicable as possible and which are not misleading, indicating that other ingredients may be present.

(f) A food shall be exempt while held for sale from the requirements of clause (2) of K.S.A. 65-665 (i) (requiring a declaration on the label of the common or usual name of each ingredient when the food is fabricated from two or more ingredients) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either: (1) The labeling of the bulk container plainly in view or (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to clause (2) of K.S.A. 65-665 (i). (Authorized by K.S.A. 65-665 (i) (2), K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-10. Special dietary uses. (a) The term "special dietary uses," as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(1) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of disease, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(2) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(3) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

(b) No provision of any regulation under K.S.A. 65-665 (j) shall be construed as exempting any food from any other provision of the act or regulations thereunder, including K.S.A. 65-665 (a) and (g), and, when applicable, the provisions of K.S.A. 1965 Supp. 65-668 and 65-669. (Authorized by K.S.A. 65-665 (j), K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-11. Food; labeling; artificial flavoring or coloring; chemical preservatives.

(a) (1) The term "artificial flavoring" means a flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice.

(2) The term "artificial coloring" means a coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant or other material in which such dye or pigment was naturally produced.

(3) The term "chemical preservative" means any chemical which, when added to food, tends to prevent or retard deterioration thereof; but does not include common salt, sugars, vinegars, spices or oils extracted from spices, or substances added to food by direct exposure thereof to wood smoke.

(b) A food which is subject to the requirements of K.S.A. 65-665 (k) shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all of these, as may be necessary to render such statement likely to be read by the ordinary individual under customary conditions of purchase and use of such food.

(d) A food shall be exempt from compliance with the requirements of K.S.A. 65-665 (k) if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

(e) A food shall be exempt while held for sale from the requirements of K.S.A. 65-665 (k) (requiring label statement of any artificial flavoring, artificial coloring, or chemical preservatives) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either: (1) The labeling of the bulk container plainly in view or (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to K.S.A. 65-665 (k). (Authorized by K.S.A. 65-665 (k), K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-12 to 28-21-19. Reserved.

B. WHEAT FLOUR AND RELATED PRODUCTS

28-21-20. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-20a. Flour; definition and standard of identity. The provisions of 21 C.F.R. 137.105, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to flour, white flour, wheat flour and plain flour. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-21. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-21a. Enriched flour; definition and standard of identity. The provisions of 21 C.F.R. 137.165, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to enriched flour. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-22. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-22a. Bromated flour; definition and standard of identity. The provisions of 21 C.F.R. 137.155, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to bromated flour. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-23. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-23a. Enriched bromated flour; definition and standard of identity. The provisions of 21 C.F.R. 137.160, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to enriched bromated flour. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-24. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-24a. Durum flour; definition and standard of identity. The provisions of 21 C.F.R. 137.220, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to durum flour. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-25. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-25a. Self-rising flour; definition and standard of identity. The provisions of 21 C.F.R. 137.180, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to self-rising white flour and self-rising wheat flour. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-26. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-26a. Enriched self-rising flour; definition and standard of identity. The provisions of 21 C.F.R. 137.185, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to enriched self-rising flour. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-27. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-27a. Phosphated flour; definition and standard of identity. The provisions of 21 C.F.R. 137.175, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to phosphated flour, phosphated white flour and phosphated wheat flour. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-28. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-28a. Whole wheat flour; definition and standard of identity. The provisions of 21 C.F.R. 137.200, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to whole wheat flour, graham flour and entire wheat flour. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-29. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-29a. Bromated whole wheat flour; definition and standard of identity. The provisions of 21 C.F.R. 137.205, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to bromated whole wheat flour. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-30. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-30a. Whole durum flour; definition and standard of identity. The provisions of 21 C.F.R. 137.225, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to whole durum wheat flour. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-31. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-31a. Crushed wheat; definition and standard of identity. The provisions of 21 C.F.R. 137.195, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to crushed wheat and coarse ground wheat. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-32. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-32a. Cracked wheat; definition and standard of identity. The provisions of 21 C.F.R. 137.190, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to cracked wheat. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-33. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-33a. Farina; definition and standard of identity. The provisions of 21 C.F.R. 137.300, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to farina. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-34. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-34a. Enriched farina; definition and standard of identity. The provisions of 21 C.F.R. 137.305, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to enriched farina. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-35. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-35a. Semolina; definition and standard of identity. The provisions of 21 C.F.R. 137.320, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to semolina. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-36 to 28-21-39. Reserved.

C. BAKERY PRODUCTS

28-21-40. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-40a. Bread, rolls and buns; definition and standard of identity. The provisions of 21 C.F.R. 136.110, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to bread, white bread, rolls, white rolls, buns and white buns. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-41. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-41a. Enriched bread, rolls and buns; definition and standard of identity. The provisions of 21 C.F.R. 136.115, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to enriched bread, enriched rolls and enriched buns. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-42. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-42a. Milk bread, rolls and buns; definition and standard of identity. The provisions of 21 C.F.R. 136.130, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to milk bread, milk rolls and milk buns. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-43. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-43a. Raisin bread, rolls and buns; definition and standard of identity. The provisions of 21 C.F.R. 136.160, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to raisin bread, raisin rolls or raisin buns. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-44. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-44a. Whole wheat bread, rolls and buns; definition and standard of identity. The provisions of 21 C.F.R. 136.180, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to whole wheat bread, graham bread, entire wheat bread, whole wheat rolls, graham rolls, entire wheat rolls, whole wheat buns, graham buns and entire wheat buns. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-45 to 28-21-49. Reserved.

D. MACARONI AND NOODLE PRODUCTS

28-21-50. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-50a. Macaroni products; definition and standard of identity. The provisions of 21 C.F.R. 139.110, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to macaroni products. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-51. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-51a. Milk macaroni products; definition and standard of identity. The provisions of 21 C.F.R. 139.120, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to milk macaroni products. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-52. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-52a. Whole wheat macaroni products; definition and standard of identity. The provisions of 21 C.F.R. 139.138, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to whole wheat macaroni products. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-53. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-53a. Wheat and soy macaroni products; definition and standard of identity. The provisions of 21 C.F.R. 139.140, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to wheat and soy macaroni products. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-54. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-54a. Vegetable macaroni products; definition and standard of identity. The provisions of 21 C.F.R. 139.125, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to vegetable macaroni products. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-55. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-55a. Noodle products; definition and standard of identity. The provisions of 21 C.F.R. 139.150, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to noodle products. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-56. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-56a. Wheat and soy noodle products; definition and standard of identity. The provisions of 21 C.F.R. 139.180, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to wheat and soy noodle products. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-57. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-57a. Vegetable noodle products; definition of identity. The provisions of 21 C.F.R. 139.160, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to vegetable noodle products. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-58. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-58a. Enriched macaroni products; definition and standard of identity. The provisions of 21 C.F.R. 139.115, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to enriched macaroni products. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-59. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-59a. Enriched noodle products; definition and standard of identity. The provisions of 21 C.F.R. 139.155, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to enriched noodle products. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

E. FRUIT BUTTERS, JELLIES AND PRESERVES

28-21-60. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-60a. Fruit butter; definition and standard of identity. The provisions of 21 C.F.R. 150.110, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to fruit butter. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-61. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-61a. Fruit jelly; definition and standard of identity. The provisions of 21 C.F.R. 150.140, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to fruit jelly. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-62. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-62a. Fruit preserves and jams; definition and standard of identity. The provisions of 21 C.F.R. 150.160, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to fruit preserves and jams. (Au-

thorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-63. Artificially sweetened fruit jelly; definition and standard of identity. The provisions of 21 C.F.R. 150.141, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to artificially sweetened fruit jelly. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-64. Artificially sweetened fruit preserves and jams; definition and standard of identity. The provisions of 21 C.F.R. 150.161, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to artificially sweetened fruit preserves and jams. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-65 to 28-21-69. Reserved.

F. DRESSINGS FOR FOODS

28-21-70. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-70a. Mayonnaise; definition and standard of identity. The provisions of 21 C.F.R. 169.140, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to mayonnaise and mayonnaise dressing. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-71. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-71a. French dressing; definition and standard of identity. The provisions of 21 C.F.R. 169.115, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to french dressing. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-72. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-72a. Salad dressing; definition; and standard of identity. The provisions of 21 C.F.R. 169.150, as in effect on November 1, 1979, are hereby adopted by reference and shall apply to salad dressing. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980.)

28-21-73 to 28-21-79. Reserved.

G. HAMBURGER AND PORK SAUSAGE

28-21-80. Authorized by K.S.A. 65-663, K.S.A. 1972 Supp. 65-673; effective Jan. 1, 1966; revoked Jan. 1, 1973.)

28-21-81. (Authorized by K.S.A. 65-663, K.S.A. 1972 Supp. 65-673; effective Jan. 1, 1966; revoked Jan. 1, 1973.)

28-21-82. Definitions and standards of identity for miscellaneous beef products. (a) Chopped beef or ground beef. "Chopped beef" or "ground beef" is chopped or ground fresh and/or frozen skeletal muscle of cattle without the addition of fat, as such; with or without seasoning; and shall not contain added water, binders, extenders, hearts, tongues, or muscle of the esophagus; and shall not contain more than 30% fat by laboratory analysis. When cheek meat (trimmed cheeks of the carcass of cattle) is used in the preparation of chopped or ground beef, the amount of such cheek meat shall be limited to 25%, and if in excess of that normal to one carcass, its presence shall be declared on the label in the ingredient statement required by K.S.A. 65-665 (i), if any, and otherwise contiguous to the name of the product.

(b) Hamburger. "Hamburger" is chopped or ground fresh and/or frozen skeletal muscle of cattle, with or without the addition of fat, as such, and/or seasoning; shall not contain added water, binders, extenders, hearts, tongues or muscle of the esophagus, and shall not contain more than 30% fat by laboratory analysis. Cheek meat (trimmed cheeks of the carcass of cattle) shall not exceed 25%; and if in excess of that normal to one carcass, its presence shall be declared on the label in the ingredient statement required by K.S.A. 65-665 (i), if any, and otherwise contiguous to the name of the product.

(c) Beef patties. "Beef patties" consist of chopped beef or ground beef as defined in paragraphs (a) and (b) of this section. The product may be labeled either "beef pattie," "chopped beef pattie," "ground beef pattie," or "hamburger pattie." It may be breaded in accordance with 28-21-85 in which case the product shall be labeled "breaded beef pattie," "breaded chopped beef pattie," "breaded ground beef pattie," or

"breaded hamburger pattie" and the breading ingredients shall be shown on the label.

(d) Steak. "Steak" is a single slice of fresh and/or frozen, lean, skeletal muscle of cattle with naturally accompanying fat, and in certain cuts (T-bone, round, club, rib, etc.) the naturally accompanying bone. The term "steak" shall not be used in describing any meat product or meat food product which is essentially a beef pattie in composition or appearance.

(e) Minute steaks or cubed steaks. "Minute steaks" or "cubed steaks" shall be prepared from single slices of fresh, lean skeletal muscle of cattle. The product may be tendered by cubing techniques but may not be divided or ground so as to resemble a pattie material. Cheek meat is not acceptable as a steaking material for these products. These products may be breaded in accordance with 28-21-85, in which case the product must be labeled "breaded minute steak" or "breaded cubed steak" and the breading ingredients shall be shown on the label. (Authorized by K.S.A. 65-663, K.S.A. 1972 Supp. 65-673; effective Jan. 1, 1973.)

28-21-83. Definitions and standards of identity for miscellaneous meat food products. (a) Meat food patties with additives. "Meat food patties with additives" shall contain specific meats, such as beef, veal, lamb, pork, poultry, or various combinations of such meats in their formulation. Fat content shall not exceed 30%, and one or more of the following binders or extenders may be used, which individually or collectively shall not exceed 3½% of the total ingredients in the pattie, except that isolated soy protein shall not exceed 2%: dried milk, nonfat dry milk, calcium reduced dried skim milk, cereal, vegetable starch, starchy vegetable flour, soy flour, soy protein concentrate, or isolated soy protein. Partially defatted beef and/or partially defatted pork fatty tissues may be used. Seasonings may be added, and water may be added not to exceed 10% of the formulation ingredients to facilitate chopping and mixing the ingredients. The product's finished characteristics shall be essentially that of a meat pattie. All ingredients shall be listed on required labeling contiguous to the name.

(b) Nonspecific meat food patties. Any pattie prepared with binders or extenders, not specified in 28-21-83-a, containing in excess of 3½% binders and extenders shall contain at least 70% meat in its formulation and contain no more than 30% fat. All ingredients shall be listed on required labeling contiguous to the name.

(c) Cooked patties. If patties are cooked or partially cooked, the composition of the raw mix from which they were prepared shall be used in determining whether they meet the requirements. (Authorized by K.S.A. 65-663, K.S.A. 1972 Supp. 65-673; effective Jan. 1, 1973.)

28-21-84. Definitions and standards of identity for miscellaneous pork products. (a) Partially defatted pork fatty tissue. "Partially defatted pork fatty tissue" is a pork by-product derived from the low temperature rendering (not exceeding 120° F.) of fresh pork fatty tissue. Such product shall have a pinkish color and a fresh odor and appearance.

(b) Pork tenderloin or pork tender. "Pork tenderloin" shall be prepared from fresh psoas muscle found on each side of the vertebral column of hogs. This product may be labeled "pork tenderloin" or "pork tender." It may be breaded in accordance with 28-21-85, in which case the product shall be labeled "breaded pork tenderloin" or "breaded pork tender" and the breading ingredients shall be shown on the label. If the product is breaded, it shall be treated for control of trichinae.

(c) Pork pattie. A "pork pattie" shall consist of chopped or ground skeletal muscle of hogs, either fresh or frozen, and shall not contain added water, binders, extenders, or more than 40% actual fat. The product may be labeled "pork pattie" and may be breaded in accordance with 28-21-85, in which case the product shall be labeled "breaded pork pattie" and the breading ingredients shall be shown on the label. If the product is breaded, it shall be treated for control of trichinae.

(d) Pork steak. "Pork steak" is a single slice of fresh and/or frozen, lean, skeletal muscle of hogs with the naturally accompanying fat and in certain cuts the naturally accompanying bone. The term "steak" shall not be used in describing any meat product or meat food product which is essentially a pork pattie in composition or appearance. (Authorized by K.S.A. 65-663, K.S.A. 1972 Supp. 65-673; effective Jan. 1, 1973.)

28-21-85. Breaded products. Breaded products. The amount of batter and breading used as a coating for breaded products shall not exceed 30 percent of the weight of the finished breaded product. (Authorized by K.S.A. 65-663, K.S.A. 1972 Supp. 65-673; effective Jan. 1, 1973.)

28-21-86 to 28-21-89. Reserved.

H. MILK AND MILK PRODUCTS

28-21-90. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-90a. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980; revoked May 10, 1996.)

28-21-91. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-91a to 28-21-91b. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980; revoked May 10, 1996.)

28-21-92. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-92a. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980; revoked May 10, 1996.)

28-21-93. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-93a. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980; revoked May 10, 1996.)

28-21-94. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-94a. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980; revoked May 10, 1996.)

28-21-95 and 28-21-96. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-96a. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980; revoked May 10, 1996.)

28-21-97 and 28-21-98. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-98a. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980; revoked May 10, 1996.)

28-21-99. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-99a. (Authorized by K.S.A. 1979 Supp. 65-663; effective May 1, 1980; revoked May 10, 1996.)

28-21-100 and 28-21-101. (Authorized by K.S.A. 1979 Supp. 65-663, 65-673; effective Jan. 1, 1966; revoked May 1, 1980.)

28-21-102 to 28-21-107. (Authorized by K.S.A. 65-663, K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966; revoked May 10, 1996.)

28-21-108. (Authorized by K.S.A. 1968 Supp. 65-673; effective Jan. 1, 1969; revoked May 10, 1996.)

28-21-109 to 28-21-111. (Authorized by K.S.A. 1968 Supp. 65-673; effective Jan. 1, 1969; revoked May 10, 1996.)

28-21-112. (Authorized by K.S.A. 1968 Supp. 65-673; effective Jan. 1, 1969; revoked May 10, 1996.)

28-21-113 to 28-21-199. Reserved.

I. DRUGS AND THERAPEUTIC DEVICES

28-21-200. Drugs; name. (a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

(b) The term "drug defined in an official compendium" means a drug having the identity prescribed for a drug in an official compendium.

(c) A statement that a drug defined in an official compendium differs in strength, quality, or purity from the standard of strength, quality, or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference. (Authorized by K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-201. Drugs and devices; labeling, misbranding. (a) Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or a food or cosmetic.

(b) The labeling of a drug which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such drug in such labeling by a name which includes

or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling. (Authorized by K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-202. Drugs and devices; labeling requirements. (a) If a drug or device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such drug or device, such as "manufactured for and packed by _____," "distributed by _____," or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs, or distributes a drug or device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such drug or device was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any drug or device from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents of a package of a drug shall reveal the quantity of such drug in the package, exclusive of wrappers and other material packed with such drug.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers and users of such drug to express quantity thereof and which give accurate information as to such quantity. But if no general usage in expressing accurate information as to the quantity of such drug exists among consumers and users thereof, the statement of the quantity of a drug which is not in tablet, capsule, ampule, or other unit form shall be in terms of weight if the drug is solid, semisolid, or viscous, or in terms of measure if the drug is liquid; the statement of the quantity of a drug which is in such unit form shall be in terms of the numerical count of such units, supplemented, when necessary to give accurate information as to the quantity of such drug in the package, by such statement (in such terms, manner, and form as are not misleading) of the weight or measure of such units, or of the quantity of each active ingredient in each such unit, as will give such information.

(3) The statement of the quantity of a device shall be expressed in terms of numerical count.

(f) A statement of weight shall be in terms of the avoirdupois pound, ounce, and grain, or of the kilogram, gram, and milligram. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, fluid ounce, and fluid dram subdivisions thereof, or of the liter, milliliter, or cubic centimeter, and shall express the volume at 68° Fahrenheit (20° centigrade).

(g) Statements of the quantity of a drug shall contain only such fractions as are generally used in expressing the quantity of such drug. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

(h) (1) Unless made in accordance with the provisions of subparagraph (2) of this paragraph, a statement of the quantity of a drug, in the terms of weight or measure applicable to such drug under the provisions of paragraph (e) (2) of this section, shall express the number of the largest unit specified in paragraph (f) of this section which is contained in the package (for example, the statement of the label of a package which contains one pint of a drug shall be "1 pint," and not "16 fluid ounces"). Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for example, 1¼ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in such paragraph [f]) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for example, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint").

(2) In the case of a drug with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be

made in accordance with such custom if it is informative to consumers.

(i) The statement of the quantity of a drug or device shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement, except in the case of ampuls, shall be considered to express the average quantity. The statement of the quantity of a drug in ampuls shall be considered to express the minimum quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure of a drug caused by ordinary and customary exposure, after such drug is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large. In the case of a liquid drug in ampuls the variation above the stated measure shall comply with the excess volume prescribed by the national formulary for filling of ampuls.

(k) Where the statement does not express the minimum quantity:

(1) Variations from the stated weight or measure of a drug shall be permitted when caused by ordinary and customary exposure, after such drug is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) Variations from the stated weight, measure, or numerical count of a drug or device shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting the contents of individual packages which occur in good packing practice. But under subparagraph (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the drug or device is below the quantity stated and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this regulation in the case of each shipment or under delivery shall be determined by the facts in such case.

(m) A drug or device shall be exempt from compliance with the requirements of clause (2) of K.S.A. 65-669 (b):

(1) The statement of the quantity of the contents, as expressed in terms applicable to such drug or device under the provisions of paragraph (e) (2) of this section, together with all other words, statements, and information required by or under authority of the act to appear on the label of such drug or device, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of K.S.A. 65-669 (c) and regulations promulgated thereunder, or

(2) The quantity of the contents of the package, as expressed in terms of the numerical count in compliance with paragraph (e) (2) or (3) of this section, is less than six units, and such units can be easily counted without opening the package, or

(3) It is an ointment, is labeled "sample" or "physician's sample," or with a substantially similar statement, and the contents of the package do not weigh more than eight grams. (Authorized by K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-203. Drugs and devices; forms of making required statements. (a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by K.S.A. 65-669 (c) by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is

not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under K.S.A. 65-669 (b) or (e) shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by K.S.A. 65-669 (c); or

(3) The use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language. (Authorized by K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-204. Habit-forming drugs; label requirements. (a) (1) The name of a substance or derivative required to be borne on the label of a drug by K.S.A. 65-669 (d) shall be the common or usual name of such substance or derivative, unless it is designated solely by a name recognized in an official compendium and such designation complies with the provisions of K.S.A. 65-669 (c).

(2) A statement on the label of a drug of the name of a constituent, which constituent is a chemical derivative of a substance named in K.S.A. 65-669 (d), shall show the substance from which such constituent is derived and that such constituent is a derivative thereof.

(b) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of such substance or derivative contained therein shall express the weight or measure of such substance or derivative in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance or derivative in a specified unit of weight or measure of the drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(c) The names and quantities or proportions of all such substances and derivatives, and the statement "warning—may be habit forming," shall immediately follow (without intervening written, printed, or graphic matter) the name by which such drug is titled in the part or panel of the label thereof which is presented or displayed under customary conditions of purchase.

(d) A drug shall not be considered to be misbranded by reason of failure of its label to bear the statement "warning—may be habit forming":

(1) If such drug is not suitable for internal use, and is distributed and sold exclusively for such external use as involves no possibility of habit formation; or

(2) If the only substance or derivative subject to K.S.A. 65-669 (d) contained in such drug is chlorobutanol, which is present solely as a preservative and in a quantity not more than 0.5 percent by weight, and such drug is for parenteral use only; or

(3) If the only substance or derivative subject to K.S.A. 65-669 (d) contained in such drug is chlorobutanol, which is present as an analgesic or as an analgesic and a preservative in a quantity not more than 3.0 percent, and such drug contains one or more other active ingredients and is for parenteral use only. (Authorized by K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-205. Drugs; statement of ingredients and proportion. (a) (1) The name of an ingredient, substance, derivative, or preparation required by K.S.A. 65-669 (e) (1) (ii) to be borne on the label of a drug shall be the name thereof, which is listed in K.S.A. 65-669 (e) (1) (ii), or, if not so listed, shall be a specific name and not a

collective name. But if an ingredient is an article the name of which is recognized in an official compendium and such article complies with the specifications set forth therefor in such compendium, such ingredient may be designated on the label of such drug by the common or usual name under which such specifications are so set forth.

(2) Where an ingredient contains a substance the quantity or proportion of which is required by K.S.A. 65-669 (e) (1) (ii) to appear on the label, and such ingredient is not a derivative or preparation of such substance as defined in paragraph (b) (1) of this section, the label shall bear, in conjunction with the name of the ingredient, a statement of the quantity or proportion of such substance in such drug.

(3) An abbreviation or chemical formula shall not be considered to be a common or usual name. The name "acetophenetidin" shall be considered to be the same as the name "acetphenetidin," "aminopyrine" the same as "amidopyrine." The name "alcohol" without qualification, means ethyl alcohol.

(b) (1) A derivative or preparation of a substance named in K.S.A. 65-669 (e) (1) (ii) is an article which is derived or prepared from such substance by any method, including actual or theoretical chemical action.

(2) A statement on the label of a drug of the name of an ingredient thereof, which ingredient is a derivative or preparation of a substance named in K.S.A. 65-669 (e) (1) (ii), shall show the substance from which such ingredient is derived or prepared and that such ingredient is a derivative or preparation thereof.

(c) (1) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of a substance, derivative, or preparation contained therein shall express the weight or measure of such substance, derivative, or preparation in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance, derivative, or preparation in a specified unit of weight or measure of the drug, or the percentage of such substance, derivative, or preparation in such drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(2) A statement of the percentage of alcohol shall express the percentage of absolute alcohol at 60° Fahrenheit (15.56° Centigrade). A statement of the percentage of a substance, derivative, or preparation other than alcohol shall express the percentage by weight; except that if both the substance, derivative, or preparation and the drug containing it are liquid, the statement may express the percentage by volume at 68° Fahrenheit (20° Centigrade), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(d) In case a statement of the quantity or proportion of a derivative or preparation in a drug is not as informative, to consumers or users of such drug, of the activity or consequences of use thereof as a statement of the quantity or proportion of the substance from which such derivative or preparation is derived or prepared, the quantity or proportion of such substance shall also be stated on the label of such drug.

(e) A label of a drug may be misleading by reason (among other reasons) of:

(1) The order in which the names of ingredients, substances, derivatives, or preparations appear thereon, or the relative prominence otherwise given such names; or

(2) Its failure to reveal the proportion of, or other fact with respect to, an ingredient, substance, derivative, or preparation, when such proportion or other fact is material in the light of the representation that such ingredient, substance, derivative, or preparation is a constituent of such drug.

(f) (1) A drug shall be exempt from the requirements of clause (1) (ii) of K.S.A. 65-669 (e) if all words, statements, and other information required by or under authority of the act to appear on the label of such drug, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of K.S.A. 65-669 (c) and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by such clause (1) (ii), such statement of the quantity of the contents shall be omitted as authorized by paragraph (m) of regulation 28-21-202 and the information required by such clause (1) (ii) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(2) A drug shall be exempt from the requirements of clause (1) (ii) of K.S.A. 65-669 (e) with respect to the alkaloids atropine, hyoscine or hy-

oscyamine contained in such drug, if such alkaloid is contained therein as a constituent of belladonna, hyoscyamus, scopola, stramonium, or other plant material, or any preparation thereof, which was used as an ingredient of such drug, and no practical and accurate method of analysis exists for the quantitative determination of each such alkaloid in such ingredient. But such exemptions shall be on the condition that the label of such drug shall state the quantity or proportion of total alkaloids contained therein as constituents of such ingredient. (Authorized by K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-206. Drugs and devices; directions for use. (a) *Adequate directions for use.* "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specifications of:

(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(2) Quantity of dose (including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions).

(3) Frequency of administration or application.

(4) Duration of administration or application.

(5) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors).

(6) Route or method of administration or application.

(7) Preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

(b) *Exemption for prescription drugs.* A drug subject to the requirements of K.S.A. 65-669 (q) shall be exempt from K.S.A. 65-669 (f) (1) if all the following conditions are met:

(1) The drug is: (I) in the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or (II) in the possession of a retail, hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs; and is to be dispensed in accordance with K.S.A. 65-669 (q).

(2) The label of the drug bears: (I) The statement "Caution: Federal law prohibits dispensing without prescription;" and (II) the recommended or usual dosage; and (III) the route of administration, if it is not for oral use; and (IV) if it is fabricated from two or more ingredients and is not designated conspicuously by a name recognized in an official compendium, the quantity or proportion of each active ingredient, and if it is not for oral use the names of all other ingredients. *Provided, however,* That the information referred to in subdivisions (II), (III), and (IV) of this subparagraph may be contained in the labeling on or within the package from which it is to be dispensed, and, in the case of ampuls too small or otherwise unable to accommodate a label but which are packaged in a container from which they are withdrawn for dispensing or use, the information referred to in subdivision (I) of this subparagraph may be placed on the outside container only.

(3) The labeling of the drug (which may include brochures readily available to licensed practitioners) bears information as to the use of the drug by practitioners licensed by law to administer it: *Provided, however,* That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to administer the drug.

(c) *Exemption for veterinary drugs.* A drug intended solely for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from K.S.A. 65-669 (f) (1) if all the following conditions are met:

(1) The drug is in the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veteri-

narian for use in the course of his professional practice.

(2) The label of a drug bears: (I) The statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian"; and (II) the recommended or usual dosage; and (III) the route of administration, if it is not for oral use; and (IV) the quantity or proportion of each active ingredient if it is fabricated from two or more ingredients and is not designated conspicuously by a name recognized in an official compendium. *Provided, however,* That the information referred to in subdivisions (II), (III), and (IV) of this subparagraph may be contained in the labeling on or within the package from which it is to be dispensed.

(3) The labeling of the drug (which may include brochures readily available to licensed veterinarians) bears information as to use of the drug by licensed veterinarians: *Provided, however,* That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among veterinarians licensed by law to administer such drug.

(d) *Exemption for prescription devices.* A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from K.S.A. 65-669 (f) (1) if all the following conditions are met:

(1) The device is in the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device and is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(2) The label of the device (other than surgical instruments) bears: (I) The statement "Caution: Federal law restricts this device to sale by or on the order of a _____," the blank to be filled with the word "physician," "dentist," "veterinarian," or with the descriptive designation of any other practitioner licensed by the law of Kansas; and (II) the method of its application or use.

(3) The labeling of the device (which may include brochures readily available to licensed practitioners) bears information as to the use of the device by practitioners licensed by law to use it or direct its use: *Provided, however,* That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to use or order the use of such device.

(e) *Exemptions for drugs and devices shipped directly to licensed practitioners, hospitals, clinics, or public-health agencies for professional use.* Except as provided in paragraph (g) of this section, a drug or device shipped directly to or in the possession of a practitioner licensed by law to administer the drug or to use or direct the use of the device, or shipped directly to or in the possession of a hospital, clinic, or public-health agency, for use in the course of the professional practice of such a licensed practitioner, shall be exempt from K.S.A. 65-669 (f) (1) if it meets the conditions of paragraphs (b) (2) and (3), or (c) (2) and (3), or (d) (2) and (3) of this section.

(f) *Retail exemption for veterinary drug and prescription devices.* A drug or device subject to paragraph (c) or (d) of this section shall be exempt at the time of delivery to the ultimate purchaser or user from K.S.A. 65-669 (f) (1) if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

(g) *Exemption for new drugs.* A new drug shall be exempt from K.S.A. 65-669 (f) (1):

(1) To the extent to which such exemption is claimed in an effective application with respect to such drug under section 505 of the federal act; or

(2) If no application under section 505 of the federal act is effective with respect to such drug but it complies with section 505 (i) and regulations thereunder.

No exemption shall apply to any other drug which would be a new drug if its labeling bore representations for its intended uses.

(h) *Exemption for drugs or devices when directions are commonly known.* A drug or device shall be exempt from K.S.A. 65-669 (f) (1) insofar as adequate directions for common uses thereof are known to the ordinary individual.

(i) *Exemptions for inactive ingredients.* A harmless drug that is ordinarily used as an inactive ingredient, such as a coloring, emulsifier, excipient, flavoring, lubricant, preservative, or solvent, in the preparation of other drugs shall be exempt from K.S.A. 65-669 (f) (1). This exemption shall

not apply to any substance intended for a use which results in the preparation of a new drug, unless an effective new-drug application provides for such use.

(j) *Exemption for diagnostic reagents.* A drug intended solely for use in the professional diagnosis of disease and which is generally recognized by qualified experts as useful for that purpose shall be exempt from K.S.A. 65-669 (f) (1) if its label bears the statement "diagnostic reagent—for professional use only."

(k) *Exemption for prescription chemicals and other prescription components.* A drug prepared, packaged, and primarily sold as a prescription chemical or other component for use by registered pharmacists in compounding prescriptions or for dispensing in dosage unit form upon prescriptions shall be exempt from K.S.A. 65-669 (f) (1) if all the following conditions are met:

(1) The drug is an official liquid acid or official liquid alkali, or is not a liquid solution, emulsion, suspension, tablet, capsule, or other dosage unit form; and

(2) The label of the drug bears: (I) The statement "for prescription compounding;" and (II) if in substantially all dosage forms in which it may be dispensed it is subject to K.S.A. 65-669 (q) (A), the statement "Caution: Federal law prohibits dispensing without prescription;" or (III) if it is not subject to K.S.A. 65-669 (q) (A) and is by custom among retail pharmacists sold in or from the package for use by consumers, "adequate directions for use" in the conditions for which it is so sold. *Provided, however,* That the information referred to in subdivision (III) of this subparagraph may be contained in the labeling on or within the package from which it is to be dispensed.

(3) This exemption shall not apply to any substance intended for use in compounding which results in a new drug, unless an effective new-drug application covers such use of the drug in compounding prescriptions.

(l) *Exemption for processing, repacking, or manufacture.* A drug in a bulk package (except tablets, capsules, or other dosage unit forms) or a device intended for processing, repacking, or use in the manufacture of another drug or device shall be exempt from K.S.A. 65-669 (f) (1) if its label bears the statement "Caution: For manufacturing, processing, or repacking;" and, if in substantially all dosage forms in which it may be dispensed it is subject to section 15 (k) (1) of the act, the statement "Caution: Federal law prohibits dispensing without prescription." This exemption and the exemption under paragraph (k) of this section may be claimed for the same article. But the exemption shall not apply to a substance intended for a use in manufacture, processing, or repacking which causes the finished article to be a new drug, unless:

(1) An effective new-drug application held by the person preparing the dosage form or drug for dispensing covers the production and delivery to him of such substance; or

(2) If no application is effective with respect to such new drug, the label statement "Caution: For manufacturing, processing, or repacking" is immediately supplemented by the words "in the preparation of a new drug limited by federal law to investigational use," and the delivery is made for use only in the manufacture of such new drug limited to investigational use as provided in federal regulation 1.114.

(m) *Exemption for drugs and devices for use in teaching, research, and analysis.* A drug or device subject to paragraph (b), (c), or (d) of this section shall be exempt from K.S.A. 65-669 (f) (1) if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, research, analysis, or testing.

(n) *Expiration of exemptions.* (1) If a shipment or delivery, or any part thereof, of a drug or device which is exempt under the regulations in this section is made to a person in whose possession the article is not exempt, or is made for any purpose other than those specified, such exemption shall expire, with respect to such shipment or delivery or part thereof, at the beginning of that shipment or delivery. The causing of an exemption to expire shall be considered an act which results in such drug or device being misbranded unless it is disposed of under circumstances in which it ceases to be a drug or device.

(2) The exemptions conferred by paragraphs (i), (j), (k), (l), and (m) of this section shall continue until the drugs or devices are used for the purposes for which they are exempted, or until they are relabeled to comply with K.S.A. 65-669 (f) (1). If, however, the drug is converted, compounded, or manufactured into a dosage form limited to prescription dispensing, no exemption shall thereafter apply to the article unless the dos-

age form is labeled as required by K.S.A. 65-669 (q) and paragraph (b), (c), or (d) of this section.

(o) *Intended uses.* The words "intended uses" or words of similar import in paragraphs (a), (g), (i), (j), and (l) of this section refer to the objective intent of the persons legally responsible for the labeling of drugs and devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstance that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug or device, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug or device introduced into commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug or device which accords with such other uses to which the article is to be put. (Authorized by K.S.A. 1965 Supp. 65-673; effective Jan. 1, 1966.)

28-21-207 to 28-21-249. Reserved.

J. MANUFACTURE AND USE OF LAETRILE

28-21-250. Definitions. (a) The term "laetrile" (with a small l) is a generic term which is used interchangeably with "Laetrile," "nitriloside," "amygdalin," "vitamin B-17" and related compounds of unknown number. The term is also used to include a number of these compounds, in which case it may appear as "laetriles."

(b) "Laetrile" (with a capital L) is a specific chemical entity with a specific chemical formula of 1-mandelonitrile-beta-glucuronic acid. This is a registered trade name.

(c) "Amygdalin" is a specific chemical entity having a specific chemical formula of D-mandelonitrile-beta-D-glucoside-6-beta-D-glucoside. Mandelonitrile is a chemical in which cyanide is combined with benzaldehyde. Amygdalin is a laetrile compound but is not "Laetrile." Only amygdalin (laetrile) has been authorized to be manufactured and used in the state of Kansas and is hereafter referred to in these regulations.

(d) The term "component" means any ingredient intended for use in the manufacture of amygdalin (laetrile) in dosage form, including those that may not appear in the finished product.

(e) The term "batch" means a specific quantity of amygdalin (laetrile) that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(f) The term "lot" means a batch or any portion of a batch of amygdalin (laetrile) or, in the case of amygdalin (laetrile) produced by a continuous process, an amount of the substance produced in a unit of time or quantity in a manner that assures its uniformity, and in either case which is identified by a distinctive lot number and has uniform character and quality within specified limits.

(g) The terms "lot number" or "control number" means any distinctive combination of letters, or numbers, or both, from which the complete history of the manufacture, control, packaging, and distribution of a batch or lot of amygdalin (laetrile) can be determined.

(h) The term "active ingredient" means any component which is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of man or other animals. The term shall include those components which may undergo chemical change in the manufacture of amygdalin (laetrile) and be present in the finished product in a modified form intended to furnish the specified activity or effect.

(i) The term "inactive ingredient" means any component other than an "active ingredient" present in the product.

(j) The term "materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

(k) The term "strength" means the concentration of the amygdalin (laetrile).

(l) The term "potency" means the therapeutic activity of amygdalin (laetrile) as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data. (Authorized by

K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-251. Manufacturing practice. (a) The criteria in each section of this regulation shall apply in determining whether the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of the product conform to or are operated or administered in conformity with current good manufacturing practice to assure that the product meets the requirements as to safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess.

(b) The regulations in this part permit the use of precision automatic, mechanical, or electronic equipment in the production and control of amygdalin (laetrile) when adequate inspection and checking procedures are used to assure proper performance. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-252. Personnel. (a) The personnel responsible for directing the manufacture and control of amygdalin (laetrile) shall be adequate in number and background of education, training and experience, or combination thereof, to assure that the product has the safety, identity, strength, quality, and purity that it purports to possess. All personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing or control operations they perform, the necessary training or experience, and adequate information concerning the reason for application of pertinent provisions of this part to their respective functions.

(b) Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of the product shall be excluded from direct contact with the product until the condition is corrected. All employees shall be instructed to report to supervisory personnel any condition that may have such an adverse effect on the product. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-253. Buildings or facilities. (a) Buildings shall be maintained in a clean and orderly manner and shall be of suitable size, construction, and location to facilitate adequate cleaning, maintenance, and proper operations in the manufacturing, processing, packing, labeling, or holding of amygdalin (laetrile). The buildings shall: (1) Provide adequate space for: (A) Orderly placement of equipment and materials to minimize any risk of mixups between different drugs, drug components, in-process materials, packaging materials, or labeling, and to minimize the possibility of contamination.

(B) The receipt, storage, and withholding from use of components pending sampling, identification, and testing prior to release by the materials approval unit for manufacturing or packaging.

(C) The holdings of rejected components prior to disposition to preclude the possibility of their use in manufacturing or packaging procedures for which they are unsuitable.

(D) The storage of components, containers, packaging materials, and labeling.

(E) Any manufacturing and processing operations performed.

(F) Any packaging or labeling operations.

(G) Storage of finished products.

(H) Control and production-laboratory operations.

(2) Provide adequate lighting, ventilation, and screening and, when necessary for the intended production or control purposes, provide facilities for adequate air-pressure, micro-biological, dust, humidity, and temperature controls to: (A) Minimize contamination of products by extraneous adulterants, including cross-contamination of one product by dust or particles of ingredients arising from the manufacture, storage, or handling of another product.

(B) Minimize dissemination of micro-organisms from one (1) area to another.

(C) Provide suitable storage conditions for drug components, in-process materials, and finished product in conformance with adequate stability.

(3) Provide adequate locker facilities and hot and cold water washing facilities, including soap or detergent, air drier or single service towels, and clean toilet facilities near working areas.

(4) Provide an adequate supply of potable water under continuous positive pressure in a plumbing system free of defects that could cause or contribute to contamination of product. Drains shall be of adequate size and, where connected directly to a sewer, shall be equipped with traps to prevent back-siphonage.

(5) Provide suitable housing and space for care of all laboratory animals.

(6) Provide for safe and sanitary disposal of sewage, trash, and other refuse within and from the buildings and immediate premises. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-254. Equipment. (a) Equipment used for the manufacture, processing, packing, labeling, holding, testing, or control of amygdalin (laetrile) shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction, and location to facilitate cleaning, maintenance, and operation for its intended purpose. The equipment shall: (1) Be so constructed that all surfaces that come into contact with the product shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of amygdalin (laetrile) or its components beyond the official or other established requirements.

(2) Be so constructed that any substances required for operation of the equipment, such as lubricants or coolants, do not contact the product so as to alter the safety, identity, strength, quality, or purity of the substance or its components beyond the official or other established requirements.

(3) Be constructed and installed to facilitate adjustment, disassembly, cleaning and maintenance to assure the reliability of control procedures, uniformity of production, and exclusion from the product of contaminants from previous and current operations that might affect the safety, identity, strength, quality, or purity of amygdalin (laetrile) beyond the official or other established requirements. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-255. Production and control procedures. (a) Production and control procedures shall include all reasonable precautions, including the following, to assure that the amygdalin (laetrile) produced has the safety, identity, strength, quality, and purity it purports to possess: (1) Each significant step in the process, such as the selection, weighing, and measuring of components, the addition of ingredients during the process, weighing and measuring during various stages of the processing, and the determination of the finished yield, shall be performed by a competent and responsible individual and checked by a second competent and responsible individual; or if such steps in the processing are controlled by precision automatic, mechanical, or electronic equipment, their proper performance is adequately checked by one (1) or more competent individuals. The written record of the significant steps in the process shall be identified by the individual performing these tests and by the individual charged with checking these steps. Such identifications shall be recorded immediately following completion of such steps.

(2) All containers and equipment used during the production of a batch of amygdalin (laetrile) shall be properly identified at all times to accurately and completely indicate their contents and, when necessary, the stage of processing of the batch.

(3) To minimize contamination and prevent mixups, equipment, utensils, and containers shall be thoroughly and appropriately cleaned and properly stored and have previous batch identification removed or obliterated between batches or at suitable intervals in continuous production operations.

(4) Appropriate precautions shall be taken to minimize microbiological and other contamination in the production of amygdalin (laetrile) purporting to be sterile or which by virtue of its intended use should be free from objectionable microorganisms.

(5) Appropriate procedures shall be established to minimize the hazard of cross-contamination of the product while being manufactured or stored.

(6) To assure the uniformity and integrity of the product, there shall be adequate in-process controls, such as checking the weights and disintegration times of tablets, the adequacy of mixing, the homogeneity of suspensions, and the clarity of solutions. In-process sampling shall be done at appropriate intervals using suitable equipment.

(7) Representative samples of all dosage forms of amygdalin (laetrile) shall be tested to determine their conformance with the specifications for the product before distribution.

(8) Procedures shall be instituted whereby review and approval of all production and control records, including packaging and labeling, shall be made prior to the release or distribution of a batch. A thorough investigation of any unexplained discrepancy or the failure of a batch to meet any of its specifications shall be undertaken whether or not the batch has already been distributed. This investigation shall be undertaken by a competent and responsible individual and shall

extend to other batches of the same product and other ingredients that may have been associated with the specific failure. A written record of the investigation shall be made and shall include the conclusions and followup.

(9) Returned goods shall be identified as such and held. If the conditions under which returned goods have been held, stored, or shipped prior to or during their return, or the condition of the product, its container, carton, or labeling as a result of storage or shipping, cast doubt on the safety, identity, strength, quality, or purity of the amygdalin (laetrile), the returned goods shall be destroyed or subjected to adequate examination or testing to assure that the material meets all appropriate standards or specifications before being returned to stock for warehouse distribution or repacking. If the product is neither destroyed nor returned to stock, it may be reprocessed provided the final product meets all its standards and specifications. Records of returned goods shall be maintained and shall indicate the quantity returned, date, and actual disposition of the product. If the reason for returned goods implicates associated batches, an appropriate investigation shall be made with the requirements of paragraph (8) of this section.

(10) Filters used in the manufacture, processing, or packaging of components of amygdalin (laetrile) for parenteral injection in humans shall not release fibers into such products. No asbestos-containing or other fiber-releasing filter may be used in the manufacture, processing, or packaging of such products. Filtration, as needed, shall be through a non-fiber-releasing filter. For the purpose of this regulation a non-fiber-releasing filter is defined as non-asbestos filter that, after any appropriate pre-treatment such as washing or flushing, will not continue to release fibers into the drug product or component that is being filtered. A fiber is defined as any particle with length at least three (3) times greater than its width. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-256. Components. (a) All components and other materials used in the manufacture, processing, and packaging of amygdalin (laetrile), and materials necessary for building and equipment maintenance, upon receipt shall be stored and handled in a safe, sanitary, and orderly manner. Adequate measures shall be taken to prevent mixups and cross-contamination affecting the components and final product. Components shall be withheld from use until they have been identified, sampled, and tested for conformance with established specifications and are released by a materials approval unit. Control of components shall include the following: (1) Each container of component shall be examined visually for damage or contamination prior to use, including examination for breakage of seals when indicated.

(2) An adequate number of samples shall be taken from a representative number of component containers from each lot and shall be subjected to one (1) or more tests to establish the specific identity.

(3) Representative samples of components liable to contamination with filth, insect infestation, or other extraneous contaminants shall be appropriately examined.

(4) Representative samples of all components intended for use as active ingredients shall be tested to determine their strength in order to assure conformance with appropriate speculations.

(5) Representative samples of components liable to microbiological contamination shall be subjected to microbiological tests prior to use. Such components shall not contain microorganisms that are objectionable in view of their intended use.

(6) Approved components shall be appropriately identified and retested as necessary to assure that they conform to appropriate specifications of identity, strength, quality, and purity at time of use. This requires the following: (A) Approved components shall be handled and stored to guard against contaminating or being contaminated by other drugs or components.

(B) Approved components shall be rotated in such a manner that the oldest stock is used first.

(C) Rejected components shall be identified and held to preclude their use in manufacturing or processing procedures for which they are unsuitable.

(7) Appropriate records shall be maintained, including the following:

(A) The identity and quantity of the component, the name of the supplier, the supplier's lot number, and the date of receipt.

(B) Examinations and tests performed and rejected components and their disposition.

(C) An individual inventory and record for each component used in each batch of amygdalin (laetrile) manufactured or processed.

(8) An appropriately identified reserve sample

of all active ingredients consisting of at least twice the quantity necessary for all required tests, except those for sterility and determination of the presence of pyrogens, shall be retained for at least two (2) years after distribution of the last lot incorporating the component has been completed or one (1) year after the expiration date of this last lot, whichever is longer. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-257. Product containers and their packaging materials. Suitable specifications, test methods, cleaning procedures, and, when indicated, sterilization procedures shall be used to assure that containers, closures, and other component parts of packages are suitable for their intended use. Product containers for amygdalin (laetrile) shall be cleansed with water which has been filtered through a non-fiber-releasing filter. Product containers and their components shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the product or its components beyond the official or established requirements and shall provide adequate protection against external factors that can cause deterioration or contamination of the product. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-258. Laboratory controls. Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, and test procedures to assure that components, in-processed drugs, and finished products conform to appropriate standards of identity, strength, quality and purity. Laboratory controls shall include:

(1) The establishment of master records containing appropriate specifications for the acceptance of each lot of the components, product containers, and their components used in the production and packaging and description of the sampling and testing procedures used for them. Said samples shall be representative and adequately identified. Such record shall also provide for appropriate retesting of the components, product containers, and their components subject to deterioration.

(2) A reserve sample of all active ingredients is required.

(3) The establishment of master records, when needed, containing specifications and a description of sampling and testing procedures for in-process amygdalin (laetrile) preparations. Such samples shall be adequately representative and properly identified.

(4) The establishment of master records containing a description of sampling procedures and appropriate specifications for finished products. Such shall be adequately representative and properly identified.

(5) Adequate provisions for checking the identity and strength of amygdalin (laetrile) for all active ingredients and for assuring:

(A) Sterility of amygdalin (laetrile) purported to be sterile and freedom from objectionable micro-organisms for those products which should be so by virtue of their intended use.

(B) The absence of pyrogens for those products purporting to be pyrogen-free.

(C) That the release pattern of sustained release products is tested by laboratory methods to assure conformance to the release specifications.

(6) Adequate provision for auditing the reliability, accuracy, precision, and performance of laboratory test procedures and laboratory instruments used.

(7) A properly identified reserve sample of the finished product (stored in the same immediate container-closure system in which the product is marketed) consisting of at least twice the quantity necessary to perform all the required tests, except those for sterility and determination of the absence of pyrogens, and stored under conditions consistent with product labeling shall be retained for at least two (2) years after distribution has been completed or one (1) year after the product's expiration date, whichever is longer.

(8) Provision for retaining complete records of all laboratory data relating to each batch or lot of amygdalin (laetrile) to which they apply. Such records shall be retained for at least two (2) years after distribution has been completed or one (1) year after the product's expiration date, whichever is longer.

(9) Provision that animals shall be maintained and controlled in a manner that assures suitability for their intended use. They shall be identified and appropriate records maintained to determine the history of use.

(10) Provision that firms which manufacture non-penicillin products (including certifiable antibiotic products) on the same premises or use the same equipment as that used for manufacturing penicillin products, or that operate under any circumstances that may reasonably be regarded as

conducive to contamination of other products by penicillin, shall test such non-penicillin products to determine whether any have become cross-contaminated by penicillin. Such products shall not be marketed if intended for use in man and the product is contaminated with an amount of penicillin equivalent to 0.05 (five one hundredths) unit or more of penicillin G per maximum single dose recommended in the labeling of a product intended for parenteral administration, or an amount of penicillin equivalent to 0.5 (five one tenth) unit or more of penicillin G per maximum single dose recommended in the labeling of a product intended for oral use. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-259. Stability. There shall be assurance of the stability of finished amygdalin (laetrile) products. This stability shall be:

(1) Determined by reliable, meaningful, and specific test methods.

(2) Determined on products in the same container-closure system in which they are marketed.

(3) Determined on any dry drug product that is to be reconstituted at the time of dispensing (as directed in its labeling), as well as on the reconstituted product.

(4) Recorded and maintained in such manner that the stability data may be utilized in establishing product expiration dates. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-260. Expiration dating. To assure that amygdalin (laetrile) products liable to deterioration meet appropriate standards of identity, strength, quality, and purity at the time of use, the label of all such products shall have suitable expiration dates which relate to stability tests performed on them.

(1) Expiration dates appearing on the labeling shall be justified by readily available data from stability studies.

(2) Expiration dates shall be related to appropriate storage conditions stated on the labeling wherever the expiration date appears.

(3) When amygdalin (laetrile) is marketed in the dry state, for use in preparing a liquid product, the labeling shall bear expiration information for the reconstituted product as well as an expiration date for the dry product. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-261. Packaging and labeling. (a) Packaging and labeling operations shall be adequately controlled, to assure that only those products that have met the standards and specifications established in their master production and control records shall be distributed; to prevent mixups between products during filling, packaging, and labeling operations; to assure that correct labels and labeling are employed for the product; and to identify the finished product with a lot or control number that permits determination of the history of the manufacture and control of the batch. An hour, day, or shift code is appropriate as a lot or control number for all products manufactured or processed in continuous production equipment. Packaging and labeling operations shall: (1) Be separated (physically or spatially) from operations on other drugs in a manner adequate to avoid mixups and minimize cross-contamination. Two (2) or more packaging or labeling operations having amygdalin (laetrile) and other drugs, containers, or labeling similar in appearance shall not be in process simultaneously on adjacent or nearby lines unless these operations are separated either physically or spatially.

(2) Provide for an inspection of the facilities prior to use to assure that all drugs and previously used packaging and labeling materials have been removed.

(3) Include the following labeling controls: (A) The holding of labels and package labeling upon receipt pending review and proofing against an approved final copy by a competent and responsible individual to assure that they are accurate regarding identity, content, and conformity with the approved copy before release to inventory.

(B) The maintenance and storage of each type of label and package labeling representing different products, strength, dosage forms, or quantity of contents in such manner as to prevent mixups and provide proper identification.

(C) A suitable system for assuring that only current labels and package labeling are retained and that stocks of obsolete labels and package labeling are destroyed.

(D) Restriction of access to labels and package labeling to authorized personnel.

(E) Avoidance of gang printing of cut labels, cartons, or inserts when the labels, cartons, or inserts are for different products or different strengths of the same products or are of the same size and have identical or similar format or color schemes. If gang printing is employed, packaging

and labeling operations shall provide for added control procedures. These added controls should consider sheet layout, stacking, cutting, and handling during and after printing.

(4) Provide strict control of the package labeling issued for use with amygdalin (laetrile). Such issue shall be carefully checked by a competent and responsible person for identity and conformity to the labeling specified in the batch production record. Said record shall identify the labeling and the quantities issued and used and shall reasonably reconcile any discrepancy between the quantity of amygdalin (laetrile) finished and the quantities of labeling issued. All excess package labeling bearing lot or control numbers shall be destroyed. In event of any significant unexplained discrepancy, an investigation should be carried out.

(5) Provide for adequate examination or laboratory testing of representative samples of finished products after packaging and labeling to safeguard against any errors in the finishing operations and to prevent distribution of any batch until all specified tests have been met. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-262. Master production and control records. Batch production and control records. (1) To assure uniformity from batch to batch, a master production and control record for each drug product and each batch size of amygdalin (laetrile) shall be prepared, dated, and signed or initialed by a competent and responsible individual and shall be independently checked, reconciled, dated, and signed or initialed by a second competent and responsible individual. The master production and control record shall include: (A) The name of the product, description of the dosage form, and a specimen or copy of each label and all other labeling associated with the retail or bulk unit, including copies of such labeling signed or initialed and dated by the person or persons responsible for approval of such labeling.

(B) The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the finished product and a statement of the total weight or measure of any dosage unit.

(C) A complete list of ingredients designated by names or codes sufficiently specific to indicate any special quality characteristic; an accurate statement of the weight or measure of each ingredient regardless of whether it appears in the finished product, except that reasonable variations may be permitted in the amount of components necessary in the preparation in dosage form provided that provisions for such variations are included in the master production and control record; an appropriate statement concerning any calculated excess of an ingredient; an appropriate statement of theoretical weight or measure at various stages of processing; and a statement of the theoretical yield.

(D) A description of the containers, closures, and packaging and finishing materials.

(E) Manufacturing and control instructions, procedures, specifications, special notations, and precautions to be followed.

(2) The batch production and control record shall be prepared for each batch of amygdalin (laetrile) produced and shall include complete information relating to the production and control of each batch. These records shall be retained for at least two (2) years after the batch distribution is complete, or at least one (1) year after the batch expiration date, whichever is longer. These records shall identify the specific labeling and lot or control numbers used on the batch and shall be readily available during such retention period. The batch record shall include: (A) An accurate reproduction of the appropriate master formula checked, dated, and signed or initialed by a competent and responsible individual.

(B) A record of each significant step in the manufacturing, processing, packaging, labeling, testing, and controlling of the batch, including: Dates; individual major equipment and lines employed; specific identification of each batch of components used; weights and measures of components and products used in the course of processing; in-process and laboratory control results; and identifications of the individual(s) actively performing and the individual(s) directly supervising or checking each significant step in the operation.

(C) A batch number that identified all the production and control documents relating to the history of the batch and all lot or control numbers associated with the batch.

(D) A record of any investigation made. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-263. Distribution records. (a) Finished goods warehouse control and distribution procedures shall include a system by which the distribution of each lot of amygdalin (laetrile) can be readily determined to facilitate its recall if necessary. Records within the system shall contain the name and address of the consignee, date and quantity shipped, and lot or control number of the product. Records shall be retained for at least two (2) years after the distribution of the product has been completed or one (1) year after the expiration date of the product, whichever is longer.

(b) To assure the quality of the product, finished goods warehouse control shall also include a system whereby the oldest approved stock is distributed whenever possible. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-264. Complaint files. Records shall be maintained of all written and oral complaints regarding each product. An investigation of each complaint shall be made. The record of each investigation shall be maintained for at least two (2) years after distribution of the product has been completed or one (1) year after the expiration date of the product, whichever is longer. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-265. Reference laboratory control. (a) Manufacturers of amygdalin (laetrile) shall submit to the state department of health and environmental laboratories, prior to release of any lot number of amygdalin (laetrile) to wholesalers or physicians, 10 (ten) ampules or vials of injectable amygdalin (laetrile) and 25 (twenty-five) tablets and capsules of each dosage size produced from each lot number of amygdalin (laetrile) produced.

(b) Manufacturers of amygdalin (laetrile) shall certify in writing which shall accompany control samples of each lot number submitted to the state department of health and environmental laboratories that the product is free of bacterial and fungal contamination, pyrogenic agents, and all adulterants including but not limited to isopropyl and methyl alcohols. Autoclaving which causes stereochemical inversion of the mandelonitrile portion of amygdalin shall not be permitted.

(c) Any lot number of amygdalin (laetrile) found to contain impurities, microbial or fungal contamination, pyrogens, or other toxic substances shall be destroyed immediately. No lot number of amygdalin (laetrile) shall be released for distribution and use until approved and certified by the secretary of health and environment. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-266. Special packaging requirements. Each vial or ampule of injectable amygdalin and each vial or container of tablets or capsules shall contain a package insert with complete description of the product including potency, adverse reactions, contra-indications, dosage recommendations, mode of administration, and other information as may be required. In packaging amygdalin (laetrile) for direct patient usage, a patient package insert must also be enclosed which summarizes the potential risks of the product. All tablets or capsules shall be packaged in child-proof containers. A precautionary label shall be attached to all packaging of injectable amygdalin (laetrile) warning patients against taking the parenteral preparation by mouth, since the high concentration can be rapidly fatal. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-267. Registration and renewal of registration. (a) Any pharmaceutical firm desiring to manufacture amygdalin (laetrile) in the state of Kansas shall file an application for a permit with the secretary of health and environment. Such application shall be accompanied by a fee of $2,500 (two thousand five hundred dollars) for the purpose of paying for the costs involved in administering this program. The permit shall be effective for one (1) year after the date of its issuance and may be renewed annually by the permit holder for a fee of $1,000 (one thousand dollars). No permits or renewal of permits shall be issued unless such fees have been collected. In addition to the permit fee the manufacturer shall be responsible for all costs incurred by the state department of health and environment for laboratory analysis and testing of each lot number of amygdalin (laetrile) submitted to the department for its approval and certification by the secretary of health and environment.

(b) The secretary of health and environment, after giving notice and holding a hearing, may revoke, suspend, or refuse to renew the permit of any person who violates any rule or regulation adopted by the secretary of health and environment or who is subject to applicable civil or crim-

inal sanctions under the federal food, drug, and cosmetic act.

(c) No person, other than a physician, may sell, offer for sale, distribute, or dispense to the public within this state amygdalin (laetrile) unless said person is currently licensed to dispense by the Kansas board of pharmacy and first obtains a permit from the secretary of health and environment authorizing the permit holder to sell, offer for sale, distribute, or dispense amygdalin (laetrile) to the public. Selling, offering for sale, or distributing amygdalin (laetrile) to the public without a valid prescription of a physician to do so shall constitute a class B misdemeanor.

(d) Application for a permit to sell, offer for sale, or dispense amygdalin (laetrile) to the public must be filed with the secretary of health and environment and shall be accompanied by a fee of $10 (ten dollars) for the purpose of paying for the costs in administering this program. The permit shall be effective for one (1) year after the date of its issuance and may be renewed annually by the permit holder for a fee of $10 (ten dollars). No permits or renewal of permits shall be issued unless such fees have been collected.

(e) Any person who sells, dispenses, or administers amygdalin (laetrile) to the public shall maintain complete records of same on forms provided by the secretary of health and environment. (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

28-21-268. Price and fee control. (a) The maximum reasonable price at which amygdalin (laetrile) may be sold to a pharmacist or direct to a physician licensed in the state of Kansas shall be based on cost of production for the product plus 25% (twenty-five percent). A cost of production analysis report which has been approved by a certified public accountant shall be submitted to the secretary of health and environment prior to establishment of the wholesale cost of the product.

(b) No increase over and above the wholesale or retail cost of amygdalin (laetrile) may be made by a physician who administers or prescribes this product. The physician may charge a fee only for his professional services in prescribing or administering amygdalin (laetrile). (Authorized by K.S.A. 1978 Supp. 65-6b06, 65-6b07; effective May 1, 1979.)

Article 22.—ENRICHMENT OF FLOUR AND BREAD

28-22-1. Enriched flour labeling. All enriched flour shall be labeled as "enriched flour." (Authorized by K.S.A. 1965 Supp. 65-2305; effective Jan. 1, 1966.)

28-22-2. Labeling of flour limited. When any reference is made on the labeling of flour to the kinds and amounts of enriching ingredients which have been added, such reference shall be limited to show the proportion of the average adult's daily requirements of such substances. (Authorized by K.S.A. 1965 Supp. 65-2305; effective Jan. 1, 1966.)

28-22-3. Labeling of flour to contain no claims for effects. Enriched flour labels shall not contain claims regarding physiological or therapeutic effects of enriching ingredients nor information concerning other minerals or vitamins. (Authorized by K.S.A. 1965 Supp. 65-2305; effective Jan. 1, 1966.)

28-22-4. Certificate of intent. A certificate of intent as provided for in section 2 of the enrichment law shall be in one of the two following forms:

(a) A continuing certificate covering all purchases for any time which shall be in the following general form:

CERTIFICATE OF INTENT

In compliance with the provisions of section 2 of the Kansas enrichment law, it is hereby certified by

_____
(Purchaser)

that all unenriched flour purchased from

_____
(Seller)

after _____ will be used only in the manufacture,
(Date)

mixing, or compounding of white bread or rolls enriched to meet the requirements of the Kansas enrichment act or of products other than flour, white bread, or rolls.

This certificate shall be cancelled only by written notice by the purchaser.

_____ _____
(Date) (Agent of purchaser)

(b) A certificate covering a single purchase order, in which case the certificate shall specify the exact quantity of flour covered by the certificate, the trade or brand names or other identifying marks on the flour containers, and any other information needed to identify the flour covered by the certificate. This type of certificate may be

made a part of any regular purchase order form used by either the purchaser or seller, provided that the certificate of intent is placed on the face of the purchase order and the order is signed by an authorized agent of the purchaser. (Authorized by K.S.A. 1965 Supp. 65-2305; effective Jan. 1, 1966.)

28-22-5. Certificate of intent available. A copy of each certificate of intent shall be retained by the purchaser and one copy kept by the seller. These certificates shall be available for examination of the duly qualified officers of the Kansas state board of health at any reasonable time. (Authorized by K.S.A. 1965 Supp. 65-2305; effective Jan. 1, 1966.)

28-22-6. Enriched bread, labeling. All enriched bread when wrapped shall be labeled "enriched bread." (Authorized by K.S.A. 1965 Supp. 65-2305; effective Jan. 1, 1966.)

28-22-7. Labeling of bread limited. When any reference is made on the labeling of bread to the kinds and amounts of enriching ingredients which have been added, such reference shall be limited to show the proportion of the average adult's daily requirements of such substance. (Authorized by K.S.A. 1965 Supp. 65-2305; effective Jan. 1, 1966.)

28-22-8. Labeling of bread to contain no claims for effects. Enriched bread labels shall not bear claims regarding physiological or therapeutic effects of enriching ingredients nor information concerning other minerals or vitamins. (Authorized by K.S.A. 1965 Supp. 65-2305; effective Jan. 1, 1966.)

Article 23.—SANITATION; FOOD AND DRUG ESTABLISHMENTS

A. GENERAL PROVISIONS

28-23-1. The cleanliness of the building in which food and drugs are prepared or distributed. Every building, room, basement, or cellar occupied or used as a confectionery, cannery, packing house, creamery, cheese factory, candy factory, ice cream factory, cake factory, restaurant, hotel kitchen, grocery, drugstore, meat market, bottling works, produce house or other place or apartment used for the preparation, manufacture, packing, storage, sale, or distribution of any food or drug shall be properly lighted, drained, plumbed and ventilated, and conducted with strict regard to the influence of such conditions upon the health of the operatives, employees, clerks, or other persons therein employed, and the purity and wholesomeness of the food therein produced. The term "food" as used herein shall include all articles used for food or drinks, confectionary or condiment, whether simple, mixed, or compound, and substances or ingredients used in the preparation thereof; and the term "drug" as used shall include all medicines and preparations for internal or external use recognized in the U.S. pharmacopoeia or national formulary, and any substance, or mixture of substances, intended to be used for the cure, mitigation, or prevention of disease of either man or animal. The term "transportation" as used shall apply only to intrastate traffic. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-2. All vehicles used in the transportation of food products shall be clean at all times. The floors, walls, ceilings, furniture, receptacles, implements, and machinery of every establishment or place where food or drugs are prepared, manufactured, packed, stored, sold, or distributed; and all cars, trucks, and vehicles, used in the transportation of food products shall at no time be kept in an unclean, unhealthy or insanitary condition. Unclean, unhealthy and insanitary conditions shall be deemed to exist if refuse, dirt and waste products subject to decomposition and fermentation incident to the manufacture, preparation, packing, storing, selling, distribution and transporting of the article of food or drug are not removed daily; if all trucks, trays, boxes, baskets, buckets, and other receptacles, chutes, platforms, racks, tables, shelves, and all knives, saws, cleavers, and other apparatus, utensils, and machinery used in moving, handling, cutting, chopping, mixing, canning, and all other processes are not thoroughly cleaned daily or immediately after a twenty-four hour interval of disuse or interruption in use, and if the clothing of operatives, employees, clerks, or other persons therein employed is unclean. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-3. All materials used in the production of food shall be protected from spoilage. All materials used in the production of food or drug products, and all food and drug products, shall be stored, handled and kept in a way to protect them from spoilage and contamination; and no material shall be used which is spoiled or con-

taminated, or which may render the finished product unwholesome or unfit for the use for which it is intended; and no water which is polluted shall be used for washing, cleaning or preparing any food product. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-4. All buildings in which food is distributed should be kept clean at all times. The walls and ceiling of every confectionery, creamery, cheese factory, hotel kitchen, and restaurant kitchen shall be well plastered, wainscoted, or ceiled with metal, or lumber, and shall be oil painted or kept well lime washed; and all interior woodwork in every confectionery, creamery, cheese factory, hotel kitchen, and restaurant kitchen shall be kept well oiled or painted with oil paints, and kept washed clean with soap and water; and every building, room, basement, or cellar occupied, or used for the preparation, manufacture, packing, storage, sale, or distribution of food shall have an impermeable floor made of cement or tile laid in cement, brick, wood or other suitable nonabsorbent material which can be flushed and washed clean with water. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-5. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966; revoked May 10, 1996.)

28-23-6. Toilet facilities. Every building, room, basement, enclosure, or premises occupied, used or maintained for the production, preparation, manufacture, canning, packing, storage, sale or distribution of food or drugs shall have adequate and convenient toilet rooms, lavatory or lavatories. The toilet room shall be separate and apart from the room or rooms where the process of production, preparation, manufacture, packing, storing, canning, selling and distribution of food is conducted. The floors of such toilet rooms shall be of nonabsorbent material, and shall be washed and scoured daily. Such toilet or toilets shall be furnished with separate venting flues and pipes, discharging into soil pipes, or shall be on the outside of and well removed from the building. Lavatories and washrooms shall be adjacent to toilet rooms, or when the toilet is outside of the building, the washroom shall be near the exit to the toilet. Lavatories and washrooms shall be supplied with soap, hot and cold water tempered by means of a mixing valve or combination faucet and clean towels, and shall be maintained in a sanitary condition. Operatives, employees, clerks, and all other persons who handle the material from which food or drugs are prepared, or the finished products, before beginning work and after visiting toilets, shall wash their hands and arms thoroughly with soap and clean water. Instructions to this effect shall be posted in a conspicuous place. (Authorized by K.S.A. 65-625, K.S.A. 1979 Supp. 65-626; effective Jan. 1, 1966; amended May 1, 1980.)

28-23-7. The cleanliness of the personnel who assist in the preparation of food for distribution. No operative, employee, or other person shall expectorate on the floor or walls of any buildings, rooms, basement or cellar where the production, manufacture, packing, storing, preparation, or sale of any food or drugs is conducted. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-8. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966; revoked May 10, 1996.)

28-23-9. Sidewalk or street display of food products; prohibitions. (a) The sidewalk or street display of meat or meat products, fresh seafood and fish, and poultry is prohibited.

(b) Food products, other than those listed in subsection (a), which ordinarily and commonly are peeled, pared or cooked in the course of preparation for consumption may be displayed in street and sidewalk displays, so long as they are in containers which are at least eighteen (18) inches above the surface of the sidewalk or street.

(c) The street or sidewalk display of all other food products is prohibited unless such products are enclosed in glass cases or otherwise enclosed to protect the products from flies, dust or other contamination. (Authorized by K.S.A. 65-625, K.S.A. 1979 Supp. 65-626; effective Jan. 1, 1966; amended May 1, 1980.)

28-23-10. Food being covered during delivery and while on display or on sale. Confectionery, dates, figs, dried fruits, berries, butter, cheese, bakery products, and all foods subject to contamination, while on sale or display are required to be properly covered to effectively protect the same from contamination by handling with hands or damage by flies, dust, vermin, or other means of foreign or injurious contamination. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-11. The condition of the building in which food is prepared or handled. No building, place, or room which is dilapidated or in such a state of repair or of such construction that it cannot be kept in a sanitary condition when used as a place for the preparation, manufacture, packing, storage, sale, or distribution of any food or drug product shall be used as a place for conducting any business handling, preparing or producing food or food products; and the owner or owners of such building, room or place shall not permit it to be used as a place for conducting such a business; and each day of use of such building, room, or place shall constitute a separate offense. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-12. The health of the personnel. No employer shall require, permit or suffer any person to work, nor shall any person work in a building, room, basement, cellar, or vehicle occupied or used for the production, preparation, manufacture, packing, storing, sale, distribution, and transportation of food or drugs, who is affected with any venereal disease, smallpox, diphtheria, scarlet fever, tuberculosis or consumption, trachoma, typhoid fever, epidemic dysentery, measles, mumps, German measles (Rothein), whooping cough, chicken pox or other contagious disease. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-13. Those responsible for the condition of the building in which food is prepared. Every person or corporation in charge of, or in control of or in authority over any of the places mentioned by and described in these regulations shall be responsible for the condition thereof, and it shall be his or its duty to see that the provisions of these regulations with reference to the condition, arrangement and conduct of such places are carried out. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-14 to 28-23-15. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966; revoked May 10, 1996.)

28-23-16. (Authorized by K.S.A. 65-626; effective, E-68-9, March 11, 1968; effective Jan. 1, 1969; amended Jan. 1, 1970; revoked Feb. 29, 2008.)

28-23-17 to 28-23-19. Reserved.

B. BAKERIES

28-23-20. "Bakery" or "bake shop" defined. The word "bakery" or "bake shop" means any place, premises, or establishment where any bakery product is prepared, processed or manufactured for sale to the general public. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-21. Definition of "bakery product." The words "bakery product" includes bread, rolls, cake, pies, cookies, and all similar goods used or intended to be used for human consumption. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-22. Condition of building which is used as a bakery. Any building occupied or used as a bakery, wherein is carried on the business of production of bakery products, shall be clean, properly lighted, drained, and ventilated. Every such bakery shall be provided with adequate plumbing and drainage facilities including suitable wash sinks, toilets, and water closets which shall be kept at all times in good working condition. All toilets and water closets shall be separate and apart from the rooms in which bakery products are produced or handled. All wash sinks, toilets, and water closets shall be kept in a clean and sanitary condition, shall be reasonably free from visible dirt and filth and shall be in well-lighted and ventilated rooms. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-23. Floors, walls and ceilings of rooms where dough is mixed. The floors, walls, and ceilings of the rooms in which the dough is mixed and handled or the pastry prepared for packing, or in which the bakery product or ingredients of such product are otherwise handled or stored shall be kept and maintained in a clean, wholesome, and sanitary condition. All openings into such rooms, including windows and doors, shall be kept properly screened or otherwise protected to exclude flies. No working rooms shall be used for any purpose other than those that are directly connected with the preparing, baking, storage, and handling of food and shall not be used as washing, sleeping, or living rooms and shall, at all times, be separated and closed from the living and sleeping rooms. Rooms shall be provided for the changing and hanging of wearing apparel apart and separate from the work rooms, and such rooms as are provided for the changing and hang-

ing of wearing apparel shall be kept clean at all times. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-24. Duties of the personnel. No employee or other person shall sit or lie upon any table, bench, trough, or shelf which is intended for the dough or bakery products. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-25. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966; revoked May 10, 1996.)

28-23-26. Cleanliness of personnel. Before beginning the work of preparing, mixing, and handling the ingredients used in baking, every person engaged in the preparation or handling of bakery products shall wash his hands and arms thoroughly and for this purpose sufficient wash basins or sinks together with soap and clean towels shall be provided by the bakery. Every such person after using the toilet and before returning to the handling of bakery products shall wash his hands and arms thoroughly. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-27. Personnel wearing sufficient clothing while working in bakery. Persons employed in bakeries must, while working, wear sufficient clothing, which clothing shall be clean and sanitary. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-28. Cleanliness of implements. All tables, shelves, troughs, trays, receptacles, utensils, implements, and machinery used in preparing, mixing, or handling bakery products or the ingredients thereof must be thoroughly cleaned daily when in use and kept in a clean and sanitary condition. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-29. Cleanliness of receptacles transporting bakery goods. Trucks, boxes, wagons, baskets and other receptacles in which bakery products are transported, stored, or held shall be kept in a clean and sanitary condition at all times and shall be free from dust, flies, and other contamination. All show cases, shelves, or other places where bakery products are sold or held shall be kept well covered, properly ventilated, well protected from dust and flies and other contamination and shall be kept in a clean and wholesome condition at all times. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-30. All waste material removed. All refuse, dirt, and waste material subject to decomposition must be removed from the bakery daily. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-31. Material used in the production or preparation of bakery products. All material used in the production or preparation of bakery products shall be stored, handled, and kept in a way to protect them from spoiling and contamination, and no material shall be used which is contaminated or which may render the bakery products unwholesome or unfit for food. The ingredients used in the production of bakery products and the sale or offering for sale of bakery products shall comply with the provisions of the laws and regulations pertaining thereto against adulteration and misbranding. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-32. All bakery products to be properly wrapped. No bakery shall permit the removal of any bakery product from a bakery unless such product shall be wrapped and sealed in clean, unused paper unprinted or printed on one side only or unless such product shall be placed in a bag which shall be sealed or closed in such a manner as to prevent the entry of dust or other form of substance, except that any such product may be delivered in a closed container to hotels, restaurants, institutions, and other bakeries and to bakery branches. Any such container as last referred to must be so constructed as to keep such product in a sanitary condition while in the process of delivery. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-33. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966; revoked May 10, 1996.)

28-23-34. No animal or fowl permitted in bakery. No animal or fowl shall be kept or allowed in any bakery or other place where bread or other bakery products are produced, handled, or stored. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-35. The water supply. The water supply of any bakery shall be ample, clean and potable. Every bakery shall make known to the inspector, and, whenever required, shall afford opportunity for inspection of the source of its water supply and the location and character of its

reservoir and sewage tanks. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-36. Approval of the Kansas state board of health. The foregoing specific rules and regulations pertaining to bakeries, etc., are in addition to the general rules and regulations adopted by the state board of health. In the event that there is any conflict between the above specific rules and regulations and the general rules and regulations adopted by the state board of health, the specific rules and regulations shall take precedence over the general rules and regulations. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-37 to 28-23-39. Reserved.

C. MANUFACTURE AND HANDLING; SODA WATER

28-23-40. (Authorized by K.S.A. 1968 Supp. 65-626; effective Jan. 1, 1966; revoked Jan. 1, 1969.)

28-23-41. Soda water defined. (a) Soda water is the class of beverages made by absorbing carbon dioxide in potable water. The amount of carbon dioxide used is not less than that which will be absorbed by the beverage at a pressure of one atmosphere and at a temperature of 60°F. It may contain buffering agents as provided in paragraph (b) (5) of this section. It either contains no alcohol or only such alcohol (not in excess of 0.5 percent by weight of the finished beverage) as is contributed by the flavoring ingredient used. Soda water designated by a name, including any proprietary name provided for in paragraph (c) of this section, which includes the word "cola" or a designation as a "pepper" beverage that, for years, has become well known as being made with kola nut extract and/or other natural caffeine-containing extracts, and thus as a caffeine-containing drink, shall contain caffeine in a quantity not to exceed 0.02 percent by weight.

(b) Soda water may contain optional ingredients, but if any such ingredient is a food additive or a color additive within the meaning of section 201(s) or (t) of the federal food, drug and cosmetic act, it is used only in conformity with a regulation established pursuant to section 409 or 706 of the act. The optional ingredients that may be used in soda water in such proportions as are reasonably required to accomplish their intended effects are:

(1) Nutritive sweeteners consisting of the dry or liquid form of sugar, invert sugar, dextrose, corn syrup, glucose syrup, sorbitol, or any combination of two or more of these.

(2) One or more of the following flavoring ingredients may be added, in a carrier consisting of ethyl alcohol, glycerin, or propylene glycol: (i) Fruit juices (including concentrated fruit juices), natural flavoring derived from fruits, vegetables, bark, buds, roots, leaves and similar plant materials. (ii) Artificial flavoring.

(3) Natural and artificial color additives.

(4) One or more of the acidifying agents acetic acid, adipic acid, citric acid, fumaric acid, lactic acid, malic acid, phosphoric acid, or tartaric acid.

(5) One or more of the buffering agents consisting of the acetate, bicarbonate, carbonate, chloride, citrate, lactate, orthophosphate, or sulfate salts of calcium, magnesium, potassium, or sodium.

(6) (i) One or more of the emulsifying, stabilizing, or viscosity-producing agents brominated vegetable oils, carob bean gum (locust bean gum), glycerol ester of wood rosin, quar gum, gum acacia, gum tragacanth, hydroxylated lecithin, lecithin, methyl-cellulose, mono- and diglycerides of fat-forming fatty acids, pectin, polyglycerol esters of fatty acids, propylene glycol alginate, sodium alginate, sodium carboxymethylcellulose, sodium metaphosphate (sodium hexametaphosphate). (ii) When one or more of the optional ingredients in subdivision (i) of this subparagraph are used, dioctyl sodium sulfosuccinate may be used in a quantity not in excess of 0.5 percent by weight of such ingredients.

(7) One or more of the foaming agents ammoniated glycyrrhizin, gum ghatti, licorice or glycyrrhiza, yucca (Joshua-tree), yucca (Mohave), quillaia (soapbark) Quillaja saponaria Molina.

(8) Caffeine, in an amount not to exceed 0.02 percent by weight of the finished beverage.

(9) Quinine in an amount not to exceed 83 parts per million by weight of the finished beverage.

(10) One or more of the chemical preservatives ascorbic acid, benzoic acid, BHA, BHT, calcium disodium EDTA, erythorbic acid, glucose-oxidase-catalase enzyme, methylparaben or propylparaben, propyl gallate, potassium or sodium benzoate, potassium or sodium bisulfite, potassium or sodium metabisulfite, potassium or sodium sorbate, sorbic acid, sulfur dioxide or tocopherols; and in the case of canned soda water, stannous chloride in a quantity not to exceed 11

parts per million calculated as tin (Sn), with or without one or more of the other chemical preservatives listed in this subparagraph.

(11) The defoaming agent dimethylpolysiloxane in an amount not to exceed 10 parts per million.

(c) (1) The name of the beverage for which a definition and standard of identity is established by this section, which is neither flavored nor sweetened, is soda water, club soda or plain soda.

(2) The name of each beverage containing flavoring and sweetening ingredients as provided for in paragraph (b) of this section is ". . . soda" or ". . . soda water" or ". . . carbonated beverage," the blank being filled in with the word or words that designate the characterizing flavor of the soda water; for example, "grape soda."

(3) If the soda water is one generally designated by a particular common name; for example, ginger ale, root beer, or sparkling water, that name may be used in lieu of the name prescribed in subparagraphs (1) and (2) of this paragraph. For the purposes of this section, a proprietary name that is commonly used by the public as the designation of a particular kind of soda water may be used in lieu of the name prescribed in subparagraphs (1) and (2) of this paragraph.

(d) Soda water that contains the optional ingredient caffeine as provided for in paragraph (b) (8) of this section, artificial flavoring, artificial coloring, or any combination of these shall be labeled to show that fact by the label statement "with . . ." or ". . . added," the blank being filled in with the word or words "caffeine," "artificial flavoring," "artificial coloring," or a combination of these words, as appropriate. If the soda water contains one or more of the optional ingredients set forth in paragraph (b) (10) of this section, which has or is intended to have a preservative effect in the finished beverage, it shall be labeled to show that fact by one of the following statements: ". . . added as a preservative" or "preserved with . . .," the blank being filled in with the common name of the preservative ingredient. If soda water contains quinine salts, the label shall bear a prominent declaration either by use of the word "quinine" in the name of the article or by separate declaration.

(e) The label statements prescribed in paragraph (d) of this section for declaring the optional ingredients present shall appear on the labeling surface of the beverage in such a manner as to render the statement likely to be read by the ordinary individual under customary conditions of purchase or use of such beverage. These statements shall immediately and conspicuously precede or follow the name of the beverage, wherever such name is prominently displayed, without intervening, written, printed or graphic matter: Provided, that, where such name is part of a trademark or brand, then other written, printed or graphic matter that is also a part of such trademark or brand may intervene if the label statements required by this section are so placed as to be conspicuously related to the name of the beverage. (Authorized by K.S.A. 65-663, K.S.A. 1968 Supp. 65-673; effective Jan. 1, 1969.)

28-23-42. "Building" defined. The term "building" as used in these rules and regulations shall mean the entire building, together with the premises. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-43. Buildings in which "soda water beverages" are manufactured. All buildings in which "soda water beverages" are manufactured shall be well lighted and ventilated; all floors, walls, ceilings, tables, benches, shelves and other fixtures, shall be maintained in such condition that they may readily be made clean and sanitary; all floors shall be watertight and shall have sufficient pitch to insure drainage. Floors may be constructed of wood, cement or tile or brick laid in cement, or any other material impermeable to water. Ceilings and walls or other overhead coverings shall be dust proof. Walls and ceilings and parts thereof shall be kept well painted, varnished or otherwise finished so that they may easily be cleaned. Walls, ceilings, doors, windows, window ledges and all other places where dirt or dust may accumulate, shall be kept cleaned at all times. All floors, fixtures, utensils, or other apparatus used in manufacture, handling, storing or sale of "soda water beverages" shall be kept clean and sanitary at all times. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-44. Premises of building. There shall be no conditions in or around or connected to building or upon the premises which will render it difficult or impossible to keep the building clean and sanitary. No cesspool or other nuisances of any kind shall be in the building or located on the premises in such a way as to affect the sanitary condition of building. No horses, cows or other animals shall be kept or stabled within 25 feet of

building. All openings, such as windows, doors, etc., shall be well screened for the purpose of excluding flies and other insects. The building shall be equipped with wash basins or sinks of sufficient size and shall be located so as to be easily accessible to all employees. Clean, individual towels shall be provided at all times. Adequate toilets shall be provided in connection with building. In cities having sewage systems, all sinks, wash basins, toilets and other drains shall be connected with said sewage system. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-45. Factory equipped with adequate and efficient machinery for washing of bottles. Every factory engaged in the manufacture of "soda water beverages" shall be equipped with adequate and efficient machinery, appliances and devices for the proper washing of all bottles and other containers in which "soda water beverages" are placed for purpose of sale. Such appliances shall include a soaker, the necessary brushes, rinsing tanks and force sprays. All soakers and such other appliances used in the cleaning of bottles and other containers must be of type approved by the chief food and drug inspector, or any of his representatives. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-46. Factory equipped with room known as a sirup and extract room. Every factory shall be equipped with a room known as a sirup and extract room, in which all sirups and extracts used shall be mixed or compounded. Such sirup and extract room shall be separated from other rooms of the factory. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-47. Bottles thoroughly cleaned. All bottles and other containers used for "soda water beverages" shall be thoroughly cleaned and sterilized before being filled; unless the bottles or other containers are used immediately after washing and sterilizing, they shall not be used. The process of cleaning shall include the soaking of such bottles or other containers in an alkali solution at a temperature of not less than 125 degrees Fahrenheit for not less than ten minutes, or for such length of time as approved by the chief food and drug inspector or his representatives. Such solution shall contain at least three percent of alkali determined as sodium hydroxide (NaOH). The alkali in such solution shall be replaced when it becomes unclean. After soaking in alkali, all bottles or other containers must be thoroughly brushed on the inside and cleaned on the outside with a brush or other suitable means, after which they must be thoroughly rinsed in clean, running water or by means of a strong spray of water under pressure. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-48. Crowns and stoppers protected from filth. All crowns or stoppers shall be so stored that they will be protected from filth, dust or other contamination, and shall be clean at the time of using. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-49. The cleanliness of containers. All sirup containers, conveyors, percolators and other products used in the manufacture of "soda water beverages" shall be kept covered and in a clean, sanitary condition at all times and all such containers, sirup lines, and siruping machines shall be flushed out with a sterilizing solution at least once a day while in daily use or on such days as they may be in use. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-50. Water used for the manufacture of "soda water beverages." All water used for the manufacture of "soda water beverages" shall be pure and free from pollution and contamination. Samples of water supply must be submitted when demanded by the chief food and drug inspector or any of his representatives. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-51. All wells and springs supplying water. All wells and springs supplying water shall be properly covered and protected so as to prevent surface contamination. All water used for the preparation of "soda water beverages" shall be properly filtered. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-52. Cleanliness of materials used. All material used shall be pure and free from adulteration. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-53. The use of saccharin. The use of saccharin is prohibited. The use of salicylic acid is prohibited. The use of benzoate of soda in quantities up to one-tenth of one percent is permissible, if so stated on the label. No coal-tar color, other than certified colors shall be used. Only harmless vegetable color is allowed to be used. All

mineral acids other than phosphoric acid are prohibited. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-54. The use of label on any package. The use in a label on any package enclosing any carbonated or uncarbonated beverage drink which contains artificial fruit flavors or artificial fruit essences of any design representing fruit, or any design, writing, expression, or device, which indicates or suggests that the contents of any such package consists wholly or in part of any natural fruit juices, is hereby prohibited. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-55. Cleanliness of personnel. All persons engaged in the handling, preparing or manufacture of "soda water beverages" shall be required to be clean in their work and shall wear clean garments. No person suffering from any communicable disease shall be employed in or about factories where "soda water beverages" are manufactured and bottled. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-56 to 28-23-59. Reserved.

D. FOOD AND DRINK STANDS; FAIRS AND PUBLIC GATHERINGS

28-23-60 to 28-23-66. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966; revoked May 10, 1996.)

28-23-67 and 28-23-68. (Authorized by K.S.A. 1979 Supp. 65-626; effective Jan. 1, 1966; revoked May 1, 1980.)

28-23-69. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966; revoked May 10, 1996.)

E. FROZEN FOOD LOCKER PLANTS

28-23-70. Frozen food locker plant defined. For the purposes of these regulations a frozen food locker plant shall mean any plant which provides locker, cabinets, boxes, baskets or other receptacles kept constantly under freezing temperatures for the storage of food products. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-71. Means for cleansing and sterilizing tools and equipment. Every frozen food locker plant shall be provided with adequate means for washing and sterilizing tools and other equipment. An adequate supply of safe water shall be provided and if hot running water is not available, means of heating shall be provided. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-72. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966; revoked May 10, 1996.)

28-23-73. Toilet and handwashing facilities. Each plant shall be provided with adequate sanitary toilets and proper hand-washing facilities. Every person handling food products in the plant shall be required to wash his hands after use of the toilets. Clean individual towels shall be provided. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-74. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966; revoked May 10, 1996.)

28-23-75. Inspection by plant operator. All food products shall be subject to the inspection of the plant operator. Any meat products showing obvious sign of disease or decomposition shall be rejected for storage. Any vegetable or fruit products showing obvious signs of decomposition or infestation with insects shall be rejected for storage. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-76 to 28-23-77. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966; revoked May 10, 1996.)

28-23-78. Products to be frozen before storage. All food products shall be completely frozen before storage in lockers. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-79. Place for processing. All processing shall be done in an enclosed or semi enclosed place, used only for the purpose of processing foods and not open to persons not engaged in the processing of foods for storage. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-80. Temperature requirements. The refrigeration system for a locker plant shall be equipped with accurate and reliable controls for the automatic maintenance of uniform temperatures: *Provided,* this shall not apply to locker plants having constant temperature supervision. Temperatures shall be maintained in the respective rooms as follows:

(a) *Chill and/or aging room.* Temperatures of thirty-seven (37) degrees F. or lower with a tolerance of ten (10) degrees for a reasonable time after fresh food is placed in the chill room.

(b) *Sharp-freeze room—sharp-freeze compartments*. Temperatures of ten (10) degrees below zero F. or lower in rooms where still air cooling is employed and temperatures of zero (0) degrees or lower in rooms where forced air circulation is employed, with a tolerance of ten (10) degrees for either type of installation for a reasonable time after putting fresh food into the freezer.

(c) *Locker room.* Temperatures of zero (0) degrees F. or lower.

The chill room, sharp-freeze room and locker room shall be equipped with accurate, direct reading thermometers or be equipped with a temperature indicator. (Authorized by K.S.A. 1965 Supp. 65-626; effective Jan. 1, 1966.)

28-23-81. (Authorized by K.S.A. 65-626; implementing K.S.A. 1984 Supp. 65-673; effective May 1, 1986; revoked Aug. 13, 1999.)

28-23-82. (Authorized by K.S.A. 65-626; implementing K.S.A. 65-673; effective May 1, 1986; amended Aug. 23, 1993; revoked Aug. 13, 1999.)

28-23-83. (Authorized by K.S.A. 65-626; implementing K.S.A. 1984 Supp. 65-673; effective May 1, 1986; revoked Aug. 13, 1999.)

28-23-84 to 28-23-87. (Authorized by K.S.A. 65-626; implementing K.S.A. 1984 Supp. 65-673; effective May 1, 1986; revoked Aug. 13, 1999.)

28-23-88. (Authorized by K.S.A. 65-626; implementing K.S.A. 65-673; effective May 1, 1986, amended, T-87-36, Nov. 19, 1986; amended May 1, 1987; revoked Aug. 13, 1999.)

28-23-89. (Authorized by K.S.A. 65-626; implementing K.S.A. 1984 Supp. 65-673; effective May 1, 1986; revoked Aug. 13, 1999.)

F. SERVING OF MILK

28-23-90 and 28-23-91. (Authorized by K.S.A. 1979 Supp. 65-626; effective Jan. 1, 1966; revoked May 1, 1980.)

Article 24.—SANITARY REGULATIONS FOR THE PRACTICE OF COSMETOLOGY, NAIL TECHNOLOGY, ELECTROLOGY, OR ESTHETICS

28-24-1. Definitions. (a) "Apprentice" has the meaning specified in K.S.A. 65-1901, and amendments thereto.

(b) "Bleach solution" means a mixture consisting of one part liquid bleach and nine parts water. The solution shall be kept in a closed container, and a fresh solution shall be made at least once every 24 hours.

(c) "Board" means the Kansas board of cosmetology.

(d) "Clean" means free from all soil and dirt and washed with soap or detergent.

(e) "Communicable disease or condition" means a disease or condition that is diagnosed by a licensed health care professional as being contagious or transmissible and that can be transmitted in the practice of cosmetology, nail technology, electrology, or esthetics.

(f) "Consumer" means a person who receives services from a licensed cosmetologist, electrologist, manicurist, esthetician, or cosmetology technician.

(g) "EPA" means the United States environmental protection agency.

(h) "Establishment" means any place licensed by the board of cosmetology where cosmetology, nail technology, electrology, or esthetics is practiced, other than a school.

(i) "FDA" means the food and drug administration of the United States department of health and human services.

(j) "Licensee" means any person licensed as a cosmetologist, cosmetology technician, manicurist, electrologist, esthetician, or instructor.

(k) "Mobile establishment" means a self-contained, enclosed mobile unit licensed for the practice of one or more of the following:

(1) Cosmetology;

(2) nail technology;

(3) esthetics; and

(4) electrology.

(l) "Noninvasive," when used to describe procedures or services, means the procedures or services confined to the nonliving cells of the epidermis found in the stratum corneum layer of the skin. The practice of cosmetology, nail technology, or esthetics shall not alter, cut, or damage any living cells.

(m) "Operator" means the person who is licensed to operate an establishment or school.

(n) "Product" means any liquid, cream, powder, spray, or other material used on the consumer in the practice of cosmetology, electrology, nail technology, or esthetics.

(o) "Protective gloves" means gloves made of

vinyl or latex or of an alternate material that provides equivalent protection.

(p) "School" means any place licensed by the board of cosmetology for the training of cosmetologists, manicurists, estheticians, electrologists, and instructors-in-training.

(q) "Single-use," when used to describe presterilized products or items, means presterilized products or items intended to be disposed of immediately after one use.

(r) "Universal precautions" means the following guidelines and controls published by the centers for disease control (CDC), which are hereby adopted by reference:

(1) "Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers: a response to P.L. 100-607, the health omnibus programs extension act of 1988," as published in morbidity and mortality weekly report (MMWR) on June 23, 1989, vol. 38, no. S-6; and

(2) "recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures," as published in morbidity and mortality weekly report (MMWR) on July 12, 1991, vol. 40, no. RR-08. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Oct. 5, 2007.)

28-24-2. Personal cleanliness. (a) Each licensee or apprentice shall thoroughly wash that person's hands with liquid soap and water or with any equally effective cleansing solution before serving each consumer.

(b) Each licensee or apprentice serving a consumer shall be clean at all times. This requirement shall include the uniform or attire worn by the licensee or apprentice. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Jan. 2, 1998; amended Oct. 5, 2007.)

28-24-3. Communicable diseases or conditions; universal precautions. (a) No licensee or apprentice afflicted with a communicable disease or condition, as defined in K.A.R. 28-24-1, shall be permitted to work or train in a school or establishment.

(b) Services shall not knowingly be performed on or by any person who has a communicable disease or condition or parasites that could be transmitted in the delivery of services under these regulations. Blood-borne diseases, including HIV infection, hepatitis B (HBV), and hepatitis C (HCV), shall not be considered infectious or contagious communicable diseases or conditions under this regulation.

(c) If there is a likelihood of exposure to blood or body fluids while practicing cosmetology, nail technology, esthetics, or electrology, the apprentice or licensee shall wear single-use protective gloves and shall adhere to universal precautions when exposed to blood or body fluids.

(d) If a blood spill occurs, the licensee or apprentice shall perform all of the following procedures:

(1) Stop service immediately;

(2) don protective gloves;

(3) clean the injured area with an antiseptic solution and cover the wound with a sterile bandage to prevent further blood exposure;

(4) double-bag and dispose of all contaminated items;

(5) clean and disinfect all equipment, tools, and implements that have come in contact with the blood; and

(6) clean the station with disinfectant. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Oct. 5, 2007.)

28-24-4. Towels, robes, and linens. (a) After a towel, robe, or linen has been used once, the licensee or apprentice shall deposit the item in a closed and labeled receptacle and shall not use the towel, robe, or linen again until the item has been properly laundered and sanitized.

(b) Each licensee or apprentice shall launder used towels, robes, and linens using either regular commercial laundering or a noncommercial laundering process in which the towels, robes, and linens are immersed in water with a temperature of at least 140 degrees Fahrenheit for at least 15 minutes during the washing or rinsing operation.

(c) Each licensee or apprentice shall store all clean towels, robes, and linens in a clean, closed, and labeled cabinet. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Jan. 2, 1998; amended Oct. 5, 2007.)

28-24-5. Headrests, shampoo bowls, treatment tables, and sinks. (a) Each licensee or apprentice shall sanitize the shampoo bowls, back bars, service chairs, manicure and treatment tables, sinks, nonporous surfaces, and workstation areas before each consumer service. Each treatment table or manicure table shall be covered with a clean sheet of examination paper or a clean towel or linen for each consumer service. Each

item, except for any single-use item, that comes into contact with skin shall be disinfected before the item is used in providing services to another consumer.

(b) Each establishment shall have at least one shampoo bowl with a shampoo spray, in working order at all times, to be used with hot and cold running water.

(c) Each school shall have at least two handwashing sinks with hot and cold running water in the work area. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Oct. 5, 2007.)

28-24-6. Bottles and containers. Each licensee or apprentice shall ensure that each bottle and container in use shall be distinctly and correctly labeled to disclose the contents. In addition, each bottle or container containing any poisonous or caustic substance shall be distinctly marked as such and shall be stored in an area that is not open to the public. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Oct. 5, 2007.)

28-24-7. Products. (a) Each licensee or apprentice shall keep all products in properly labeled, clean, and closed containers.

(b) When only a portion of a product is to be used on a consumer, the licensee or apprentice shall remove the product from a bulk supply container in a way that does not contaminate the unused portion. The licensee or apprentice shall discard any remaining portion that is not used during that consumer's service.

(c) Each licensee or apprentice shall maintain all products in a manner that keeps the products free of contaminants.

(d) A licensee or apprentice shall not use in any establishment or school any product banned or restricted by the FDA for use in cosmetology, nail technology, esthetics, or electrology. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Oct. 5, 2007.)

28-24-8. Instruments and supplies. (a) Each licensee or apprentice shall use a sanitary neck strip or towel to keep the full-length protective covering from coming in direct contact with the neck of each consumer receiving cosmetology services.

(b) Each licensee or apprentice shall dispose of any supplies or instruments that come in direct contact with a consumer and cannot be disinfected or sterilized. These supplies or instruments shall be disposed of in a covered waste receptacle immediately after the single use.

(c) Each licensee or apprentice shall immediately dispose of any single-use material coming into contact with blood or other bodily fluids. The contaminated material shall be double-bagged, sealed, and disposed of. All needles and any other sharp items shall be disposed of in a sharps container.

(d) Each sanding band used on an electric file shall be a single-use item. The licensee or apprentice shall dispose of each sanding band after it is used.

(e) In the practice of electrology, all needles shall be single-use items. The licensee or apprentice shall dispose of each needle after it is used.

(f) Each licensee or apprentice shall properly disinfect each metal bit for an electric file after each use on a consumer and then shall store the bit in a clean, closed, and labeled container until its next use.

(g) No licensee or apprentice shall be permitted to carry any instrument or supplies in or on a garment or uniform, including an instrument belt and an instrument organizer. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Oct. 5, 2007.)

28-24-9. Pedicure equipment. For the purposes of this regulation, the term "pedicure equipment" shall mean any apparatus that holds water for the purpose of pedicure service. Each cosmetologist or manicurist and each apprentice of nail technology or cosmetology shall disinfect and maintain all pedicure equipment according to this regulation.

(a) Each cosmetologist, cosmetology technician, or manicurist and each apprentice of nail technology or cosmetology shall perform all of the following:

(1) Drain the pedicure equipment of all water and remove all debris from the equipment;

(2) clean the surfaces and walls of the equipment with soap or detergent and rinse with clean warm water;

(3) circulate a bleach solution or an EPA-registered disinfectant with demonstrated bactericidal, fungicidal, virucidal, and tuberculocidal activity used according to the manufacturer's instructions through the equipment for 10 minutes and then drain and rinse the equipment with warm clean water; and

(4) wipe the equipment dry with a clean towel.

(b) At the end of each day, each cosmetologist, cosmetology technician, or manicurist and each apprentice of nail technology or cosmetology shall perform the following:

(1) Drain the pedicure equipment of all water and remove all debris from the equipment;

(2) remove all debris trapped behind any removable parts of the equipment;

(3) (A) Wash all removable parts and the inlet with soap or detergent and then with a bleach solution; or

(B) totally immerse all removable parts and the inlet in an EPA-registered disinfectant with demonstrated bactericidal, fungicidal, virucidal, and tuberculocidal activity used according to the manufacturer's instructions;

(4) replace all removable parts; and

(5) flush the equipment with soap and water for 10 minutes and then rinse, drain, and allow the equipment to air-dry.

(c) Each week, each cosmetologist, cosmetology technician, or manicurist and each apprentice shall ensure that all of the following cleaning and disinfecting procedures are followed:

(1) After the cleaning procedures specified in subsection (b) are followed, the pedicure equipment shall be filled with bleach solution, which shall be circulated through the system for five to 10 minutes before the jets are turned off.

(2) The bleach solution shall be allowed to remain in the equipment for at least six hours. Then the equipment shall be drained and flushed with warm clean water. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Oct. 5, 2007.)

28-24-10. Disinfecting nonelectrical instruments and equipment. (a) Each licensee or apprentice shall disinfect each nonelectrical instrument or piece of equipment in the following manner before it is used on a consumer:

(1) Clean the instrument or equipment with soap or detergent and with water;

(2) rinse the instrument or equipment with clean water; and

(3) use one of the following disinfection methods:

(A) Totally immerse the instrument or equipment in an EPA-registered, hospital-grade disinfectant that has demonstrated bactericidal, fungicidal, and virucidal activity when used according to the manufacturer's instructions and then rinse the instrument or equipment with clean water; or

(B) totally immerse the instrument or equipment in bleach solution for 10 minutes and then rinse the instrument or equipment with clean water.

(b) Each licensee or apprentice shall immediately disinfect each nonelectrical instrument or piece of equipment that has come in contact with blood or other body fluids. The instrument or equipment shall be disinfected in the following manner:

(1) Clean with soap or detergent and with water;

(2) rinse with clean water; and

(3) totally immerse in an EPA-registered, hospital-grade disinfectant that has demonstrated bactericidal, fungicidal, virucidal, and tuberculocidal activity when used according to the manufacturer's instructions and rinse with clean water.

(c) Each licensee and apprentice shall ensure that the disinfectant solutions or bleach solution specified in subsections (a) and (b) are prepared, available for use, and covered at all times. EPA-registered disinfectants shall be changed at least once per week or more often if the solution becomes visibly cloudy or dirty. A bleach solution shall be prepared daily or more often if the solution becomes diluted or dirty.

(d) For each disinfectant used as specified in subsections (a) and (b), one of the following shall be available at all times in the establishment or school and shall be provided upon request to the board of cosmetology or the board's designee:

(1) The manufacturer's material safety data sheet (MSDS); or

(2) the manufacturer-labeled container.

(e) Each instrument that has been used on a consumer or soiled in any manner shall be placed in a properly labeled, covered receptacle until the instrument is disinfected.

(f) All disinfected instruments shall be stored in a properly labeled, clean, enclosed cabinet or covered container reserved for clean instruments only.

(g) The electrolysis instruments and equipment that are sterilized in accordance with K.A.R. 28-24-12 shall not be subject to the requirements of this regulation. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Jan. 2, 1998; amended Oct. 5, 2007.)

28-24-11. Disinfecting electrical instru-

ments. (a) Each licensee or apprentice shall disinfect each instrument in the following manner before providing any service to each consumer:

(1) Remove all foreign matter from the instrument; and

(2) use one of the following disinfection methods:

(A) Completely saturate the portion of the electrical instrument that comes in contact with the consumer with a bleach solution or with a disinfectant liquid spray or foam that is EPA-registered and has demonstrated bactericidal, fungicidal, and virucidal activity when used according to the manufacturer's instructions; or

(B) with a bleach solution, completely saturate the portion of the electrical instrument that comes into contact with the consumer, and then rinse that portion of the electrical instrument with clean water.

(b) All electrical instruments and equipment that have come in contact with blood or other body fluids shall be disinfected immediately in the following manner:

(1) Remove all foreign matter from the instrument; and

(2) use one of the following disinfection methods:

(A) Completely saturate the portion of the electrical instrument that comes in contact with the consumer with a bleach solution or with a disinfectant liquid spray or foam that is EPA-registered and has demonstrated bactericidal, fungicidal, virucidal, and tuberculocidal activity when used according to the manufacturer's instructions; or

(B) with a bleach solution, completely saturate the portion of the electrical instrument that comes into contact with the consumer, and then rinse the instrument with clean water.

(c) Each disinfected electrical instrument shall be stored in a properly labeled, clean enclosed cabinet or covered container reserved for clean instruments only. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Oct. 5, 2007.)

28-24-12. Electrolysis instruments, equipment, and practices. Only single-use instruments or sterilized equipment shall be used on a consumer. (a) Each licensee or apprentice shall first clean all non-single-use nonelectrical instruments or equipment that comes in contact with an individual consumer by performing each of the following steps after each use with an individual consumer and before sterilization:

(1) Clean the instruments or equipment with warm, soapy water with detergent to remove visible debris;

(2) rinse and air-dry the instruments or equipment; and

(3) immerse the instruments or equipment in an ultrasonic unit that is operated in accordance with the manufacturer's instructions and that contains water and either a protein-dissolving detergent or an enzyme cleaner.

(b) Each licensee or apprentice shall ensure that all non-single-use nonelectrical instruments and equipment are sterilized by adhering to either or both of the following practices:

(1) Placing reuseable instruments in sterilization bags with color strip indicators and then placing the bags in a steam autoclave sterilizer or a dry-heat sterilizer that is approved and listed by the FDA and that is used, cleaned, and maintained according to the manufacturer's directions; or

(2) using single-use, prepackaged, sterilized instruments or equipment obtained from suppliers or manufacturers.

(c) Each steam autoclave sterilizer and each dry-heat sterilizer shall meet the following requirements:

(1) Be approved by the U.S. food and drug administration (FDA);

(2) contain visible physical indicators, including a thermometer and a timer, necessary to ensure that the steam autoclave sterilizer is functioning properly during sterilization cycles;

(3) be used with chemical indicators that change color after exposure to the sterilization process, to ensure that all sterilization requirements are met; and

(4) be cleaned, used, and maintained according to the manufacturer's instructions.

(d) Each cleaned instrument or piece of equipment shall be sterilized in accordance with the manufacturer's instructions for each specific sterilizer and by utilizing one of the following:

(1) Steam autoclave sterilizer. If a steam autoclave sterilizer is used, the instruments or equipment shall be sterilized for 15 to 20 minutes at 250 degrees Fahrenheit and the pressure shall consist of 15 to 20 pounds per square inch (psi).

(2) Dry-heat sterilizer. If a dry-heat sterilizer is used, the instruments and equipment shall be sterilized for either 60 minutes at 340 degrees

Fahrenheit or 120 minutes at 320 degrees Fahrenheit.

(e) Each operator shall use a sterilization-monitoring service or laboratory using commercially prepared spores at least monthly to ensure that all microorganisms have been destroyed and sterilization has been achieved.

(1) Each operator shall maintain a log at the establishment with the date and results of each monthly test for a minimum of three years and shall make the records available for review at any time by the board or the board's designee.

(2) A copy of the manufacturer's procedural manual for operation of the steam autoclave sterilizer or dry-heat sterilizer shall be available for inspection by the board or the board's designee.

(f) Each licensee or apprentice shall place only the single-use instrument or sterilized equipment to be used for each consumer on a clean field and shall replace the clean field with a new clean field after each consumer.

(g) Each licensee or apprentice shall dispose of each needle and any other sharp equipment in a puncture-resistant, leakproof container that can be securely closed for the handling, storage, transportation, and disposal of sharps. The container shall be red and shall be labeled with the biohazard symbol.

(h) The surface of each counter, each piece of furniture, and each piece of equipment in each area where a consumer is served shall be made of smooth, nonporous materials. Each licensee or apprentice shall clean these surfaces using either an EPA-registered disinfectant according to the manufacturer's instructions or a bleach solution. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Oct. 5, 2007.)

28-24-13. Physical facilities. (a) The operator of each school or establishment shall meet the following requirements:

(1) Keep the school or establishment well lighted and well ventilated by natural or mechanical methods that remove or exhaust fumes, vapor, or dust to prevent hazardous conditions from occurring and to allow the free flow of air in a room in proportion to the size and the capacity of the room; and

(2) keep the floors, walls, ceilings, furniture and other fixtures and apparatus, and all other exposed surfaces in each school or establishment clean, free of dust, hair and other debris, and in good repair at all times. All curtains shall be kept carefully laundered or chemically cleaned.

(b)(1) Except as provided in paragraph (b)(2), if a room used for residential purposes is also used for or is adjacent to a room used for the practice of cosmetology, nail technology, esthetics, or electrology, then a solid partition shall separate the portion of the premises used for residential purposes from the licensed area. The partition may contain a door if it remains closed, except for entering and leaving.

(2) Each establishment that has an initial license issued on or after December 31, 2007 and that is located in a residence shall have a separate, outside entrance to the establishment.

(c) If a room used for nonlicensed business purposes is also used for or is adjacent to a room used for the practice of cosmetology, nail technology, esthetics, or electrology and if the board of cosmetology, upon consultation with the secretary of health and environment, determines that the proximity of the licensed or nonlicensed activities poses a possible threat to the health of the employees, the consumers, or the public, then the operator of the school or establishment may be required by the board to meet one or both of the following requirements:

(1) A solid partition shall separate the portion of the premises used for nonlicensed business purposes from the licensed area. The partition may contain a door if it remains closed, except for entering and leaving.

(2) A separate, outside entrance shall be provided for the school or establishment.

(d) Each school or establishment shall have a safe water supply.

(e) Each establishment shall have at least one restroom. Each restroom shall include at least one working toilet and one hand-washing sink, with a liquid soap dispenser and either disposable towels or an air dryer. The operator shall keep each restroom in a sanitary condition. Each restroom shall be located within the building in which the establishment is housed.

(f) Each school shall have at least two restrooms. Each restroom shall have at least one working toilet and one hand-washing sink, with a liquid soap dispenser and either disposable towels or an air dryer. The operator shall keep each restroom in a sanitary condition.

(g) The following requirements shall apply to each mobile establishment:

(1) All equipment shall be securely anchored to the mobile establishment.

(2) No services shall be performed while the mobile establishment is in motion.

(3) Each mobile establishment shall have the following:

(A) A hand-washing sink that has hot and cold running water;

(B) a self-contained supply of potable water. The water tank shall have a capacity of at least 100 gallons, and the holding tanks shall have at least the same capacity; and

(C) one or more self-contained, recirculating, flush chemical toilets with a holding tank. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Jan. 2, 1998; amended Oct. 5, 2007.)

28-24-14. Prohibitions. (a) The following shall be prohibited in any area of an establishment or school in which consumers are provided service:

(1) Smoking, eating, possessing or consuming alcoholic beverages, or preparing food;

(2) using neck dusters or nail dusters;

(3) possessing any animal in the establishment or school. This prohibition shall not apply to any assistance dog, as defined in K.S.A. 39-1113 and amendments thereto;

(4) using a razor-type device to remove calluses or skin blemishes;

(5) using invasive skin-removal techniques, products, and practices that remove viable cells that are deeper than the stratum corneum; and

(6) placing waste in open waste containers.

(b) The operator of a school or establishment shall not permit excessive amounts of waste, refuse, or any other items that could cause a hazard to accumulate on the premises of the school or establishment. (Authorized by and implementing K.S.A. 65-1,148; effective Jan. 4, 1993; amended Jan. 2, 1998; amended Oct. 5, 2007.)

28-24-15. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Jan. 4, 1993; revoked Oct. 5, 2007.)

28-24-16. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Jan. 4, 1993; revoked Oct. 5, 2007.)

Article 24a.—SANITARY REGULATIONS FOR TANNING FACILITIES

28-24a-1. Definitions. (a) "Consumer" has the meaning specified in K.A.R. 69-12-1.

(b) "EPA" means the United States environmental protection agency.

(c) "FDA" means the United States food and drug administration.

(d) "Person" means an individual, association, corporation, or other legal entity.

(e) "Protective eyewear" means any device designed to be worn by users to reduce exposure of the eyes to the radiation emitted by the tanning device.

(f) "Tanning device operator" means an individual who controls operation of a tanning device and instructs and assists the consumer in the proper operation of the tanning device.

(g) "Tanning facility operator" means the person who is licensed to operate a tanning facility. (Authorized by and implementing K.S.A. 65-1,148 and 65-1925; effective Oct. 5, 2007.)

28-24a-2. Facility standards and practices. (a) After each use of a tanning device, a tanning device operator shall disinfect the tanning device using an EPA-registered disinfectant with demonstrated bactericidal, fungicidal, tuberculocidal, and virucidal activity when used according to the manufacturer's instructions.

(b) Each tanning device operator shall ensure that each towel distributed to a consumer or any other individual is, upon its return, deposited in a closed receptacle and not used again until laundered and sanitized.

(c) Each tanning facility operator shall ensure that the tanning facility is well lighted, well ventilated, and sanitary. (Authorized by and implementing K.S.A. 65-1,148 and 65-1925; effective Oct. 5, 2007.)

28-24a-3. Protective eyewear. Each tanning device operator shall disinfect the protective eyewear before each use. If single-use protective eyewear is used, the eyewear shall be disposed of in a covered waste receptacle immediately after use. (Authorized by and implementing K.S.A. 65-1,148 and 65-1925; effective Oct. 5, 2007.)

Article 25.—SANITARY REGULATIONS FOR BARBERS

28-25-1. Definitions. (a) "EPA" means the United States environmental protection agency.

(b) "Shop" means any place where barbering is practiced, other than a barbering school.

(c) "Licensee" means any person licensed as a barber.

(d) "School" means any place licensed by the board of barbering for the training of barbers.

(e) "Student" means a person receiving training in a school. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Aug. 23, 1993.)

28-25-2. Personal cleanliness. (a) The person and the uniform or attire worn by an individual serving a patron shall at all times be clean.

(b) Each person shall thoroughly wash his or her hands with soap and water or any equally effective cleansing solution before serving each patron. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Aug. 23, 1993.)

28-25-3. Infectious disease. (a) No person afflicted with an infectious or communicable disease, which may be transmitted during the performance of the acts of barbering shall be permitted to work or train in a school or shop.

(b) No school or shop shall require or permit a student or licensee, knowingly, to work upon a person suffering from any infectious or communicable disease which may be transmitted during the performance of the acts of barbering. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Aug. 23, 1993.)

28-25-4. Towels. (a) After a towel has once been used, it shall be deposited in a closed receptacle, and shall not again be used until properly laundered and sanitized.

(b) Used towels shall be laundered either by regular commercial laundering or by a noncommercial laundering process which includes immersion in water at 140 degrees F for not less than fifteen minutes during the washing or rinsing operation.

(c) All clean towels are to be stored in a closed cabinet or container. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Aug. 23, 1993.)

28-25-5. Headrests and shampoo bowls. (a) Clean cloth or clean tissue shall be placed on headrests before serving each patron. When the headrest is not in use, it shall be kept in a clean place, free from dust and dirt.

(b) A shampoo bowl or sink with hot and cold running water shall be near each station at which a barber is working. The water shall be supplied from an approved public water supply, with drain connected to an approved sewer system.

(c) A soap dispenser and disposable towels shall be provided near each sink or shampoo bowl.

(d) The shampoo bowl or sink shall be kept in good repair and in a clean and sanitary condition at all times. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Aug. 23, 1993.)

28-25-6. Bottles and containers. All bottles and containers in use shall be distinctly and correctly labeled to disclose their contents. All bottles containing poisonous or caustic substances shall be additionally and distinctly marked as such. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Aug. 23, 1993.)

28-25-7. Liquids, creams, powders and other preparations. (a) All liquids, creams, and other preparations shall be kept in properly labeled, clean and closed containers. Powders shall be kept in a clean shaker.

(b) When only a portion of a preparation is to be used on a patron, it shall be removed from the container in such a way as not to contaminate the remaining portion. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Aug. 23, 1993.)

28-25-8. Neck strips. The hair cloth shall never be permitted to come in direct contact with the neck of the patron. Sanitary neck strips or towels must be used at all times to prevent such contacts. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Aug. 23, 1993.)

28-25-9. Instruments and supplies. (a) All supplies and instruments which come in direct contact with a patron and cannot be disinfected shall be disposed of in a covered waste receptacle immediately after use.

(b) No person training or working in a school or establishment shall be permitted to carry any instrument or supplies in or on a garment or uniform. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Aug. 23, 1993.)

28-25-10. Disinfecting non-electrical instruments and equipment. (a) Before use upon a patron, all non-electrical instruments and equipment shall be disinfected in the following manner: clean with soap or detergent and water and then totally immerse in either an EPA-registered product that contains one of the following terms on its label: sterilant; or bactericide, fungicide and virucide; or disinfectant, fungicide and

virucide; or germicide, fungicide and virucide used according to manufacturer's instructions or 70% isopropyl alcohol for at least ten minutes.

(b) The disinfectant solutions specified in section (a) shall remain covered at all times and shall be changed at least once per week and/or whenever visibly cloudy or dirty.

(c) All non-disinfected instruments that have been used on a patron or soiled in any manner shall be placed in a properly labeled covered receptacle.

(d) All disinfected instruments shall be stored in a clean enclosed cabinet or covered container reserved for instruments only. (Authorized by and implementing K.S.A. 65-1,148; effective Aug. 23, 1993.)

28-25-11. Disinfecting electrical instruments. (a) Clippers, vibrators, and other electrical instruments shall be disinfected prior to each use by:

(1) First removing all foreign matter; and

(2) Disinfecting with an EPA-registered product that contains one of the following terms on its label: sterilant; or bactericide, fungicide and virucide; or disinfectant, fungicide and virucide; or germicide, fungicide and virucide used according to manufacturer's instructions.

(b) All disinfected electrical instruments shall be stored in a clean, covered place. (Authorized by and implementing K.S.A. 65-1,148; effective Aug. 23, 1993.)

28-25-12. Physical facilities. (a) The school or shop shall be kept well lighted, well ventilated, and in a sanitary condition. Floors, walls, ceilings, furniture and other fixtures and apparatus and all other exposed surfaces in each school or shop shall be kept clean, free from dust, hair and other debris, and in good repair at all time. All curtains shall be kept carefully laundered or chemically cleaned.

(b) If a room or rooms used for residential or non-barbering business purposes are in the same room or adjacent to a room used for the practice of barbering, then a solid partition shall separate the premises used for residential or business purposes from the barbering area. The partition may contain a door, provided it remains closed except for entering and leaving.

(c) A separate outside entrance shall be provided for the school or shop.

(d) All schools or shops shall be supplied with sanitary drinking water facilities. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Aug. 23, 1993.)

28-25-13. Prohibitions. (a) The use of cuspidors or other receptacles for sputum is prohibited. No person shall expectorate in any shop or school.

(b) The use of shaving mugs and lather brushes is prohibited.

(c) The use of lump alum, styptic sticks or pencils, powder puffs, and sponge, finger or towel bowls is prohibited.

(d) Neck dusters are prohibited.

(e) No person shall bring any animal into, or permit any animal to be brought into, or permit any animal to remain in a school or shop. Trained animals accompanying sightless or hearing impaired persons shall be exempt from this section.

(f) No school or shop shall permit an accumulation of waste or refuse.

(g) All open waste containers are prohibited. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Aug. 23, 1993.)

28-25-14. Rules and licenses posted. (a) Each school or shop shall keep a copy of the sanitation regulations adopted by the Kansas department of health and environment, the inspection report for the school or shop, and the license of the school or shop posted in a conspicuous place.

(b) Each employee or student shall post their personal license at their work station. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Aug. 23, 1993.)

28-25-15. Enforcement. (a) The holder or holders of a shop or school license and the person in charge of any such shop or school shall be liable for implementing and maintaining all applicable sanitary regulations individually and jointly with all persons employed by or working in or on the premises. All students and licensees shall be held individually liable for implementation and maintenance of all applicable sanitary regulations.

(b) Refusal to permit, or interference with, an inspection by an authorized representative of the board of barbering during any time the instruction or practice of barbering is being conducted shall constitute a cause for disciplinary action. (Authorized by and implementing K.S.A. 1991 Supp. 65-1,148; effective Aug. 23, 1993.)

Article 26.—MEAT AND POULTRY

A. SLAUGHTERHOUSES; PACKING, SAUSAGE AND OTHER PROCESSING PLANTS

28-26-1 to 28-26-19. (Authorized by K.S.A. 65-6a03; effective Jan. 1, 1966; revoked May 1, 1980.)

28-26-20 to 28-26-29. Reserved.

B. POULTRY DRESSING AND PACKING PLANTS

28-26-30 to 28-26-49. (Authorized by K.S.A. 65-6a03; effective Jan. 1, 1966; revoked May 1, 1980.)

28-26-50 to 28-26-59. Reserved.

C. STATE INSPECTION; MEAT AND POULTRY

28-26-60 to 28-26-70. (Authorized by K.S.A. 65-6a03, 65-6a07; effective Jan. 1, 1966; revoked May 1, 1980.)

28-26-71 to 28-26-79. Reserved.

D. LABELING IMPORTED MEAT AND POULTRY

28-26-80 to 28-26-87. (Authorized by K.S.A. 1965 Supp. 65-6a15; effective Jan. 1, 1966; revoked May 10, 1996.)

28-26-88 and 28-26-89. Reserved.

E. LUNGS IN FOOD PRODUCTS

28-26-90. (Authorized by K.S.A. 65-603, 65-6a03; effective Jan. 1, 1966; revoked May 1, 1980.)

28-26-90a. (Authorized by K.S.A. 1979 Supp. 65-673; effective May 1, 1980; revoked May 10, 1996.)

Article 27.—HAZARDOUS HOUSEHOLD ARTICLES

A. GENERAL REGULATIONS

28-27-1. Definitions. (a) The term "hazardous substance" as used in these regulations shall mean any substance or mixture of substances which: (1) is toxic, (2) is corrosive, (3) is an irritant, (4) is flammable, (5) is radioactive, or (6) generates pressure through decomposition, heat or other means, if such substance may cause substantial personal injury or illness during any customary or reasonably anticipated handling or use.

(b) The term "toxic" shall apply to any substance which has the inherent capacity to produce bodily injury through ingestion, inhalation, or absorption through the skin.

(c) (1) The term "poison" means any toxic substance which falls within any of the following categories: (A) produces death within forty-eight hours in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, at a single dose of fifty milligrams or less per kilogram of body weight, when orally administered; or (B) produces death within forty-eight hours in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, when inhaled continuously for a period of one hour or less at an atmospheric concentration of two milligrams or less per liter of gas, vapor, mist, or dust: *Provided,* Such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; or (C) produces death within forty-eight hours in half or more than half of a group of ten or more rabbits tested in a dosage of two hundred milligrams or less per kilogram of body weight, when administered by continuous contact with the bare skin for twenty-four hours or less.

(2) If available data on experience with either mature or immature humans with any substance in the above named concentrations indicate results different from those obtained on animals, the human data shall take precedence.

(d) The term "corrosive" means any substance which in contact with living tissue will cause substantial destruction of tissue by chemical action; but shall not refer to action on inanimate surfaces.

(e) The term "irritant" means any substance, not corrosive within the meaning of subsection (d) of this section, which in contact with normal living tissue will induce a severe local tissue reaction.

(f) The term "flammable" shall apply to any substance which has a flash point of eighty degrees Fahrenheit, or below, as determined by the Tagliabue open cup tester.

(g) The term "radioactive" shall apply to any substance which as a result of disintegration of unstable atomic nuclei emits energy.

(h) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any substance; and a requirement, made by or under authority of this act, that any word, statement, or other information appear on the label, shall not be considered to be complied with unless such word, statement, or other

information also appears on the outside container or wrapper, if any there be, of the retail package of such substance, or is easily legible through the outside container or wrapper. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-2. Labeling. Every retail package of a hazardous substance intended for household use which is offered for sale in this state, except those for which specific regulations are hereinafter provided, shall bear a label containing the following information:

(a) The name and place of business of the manufacturer, packer or distributor;

(b) The common or usual name, or the chemical name (if there be no common or usual name), or the recognized generic name (not trade name only) of the hazardous substance or of each component which contributes substantially to its hazard;

(c) One of the following signal words: "Danger," "warning," or "caution;"

(d) When necessary, an affirmative statement of the principal hazard or hazards, such as, "flammable," "vapor harmful," "causes burns," "absorbed through skin," or similar wording descriptive of the hazard.

(e) Precautionary measures describing the appropriate action to be followed or avoided;

(f) Instructions, when necessary, for first aid treatment in case of contact or exposure if the substance is hazardous through contact or exposure;

(g) The word "poison" for any substance which is defined as poisonous in these regulations;

(h) Instructions for handling and storage of packages which require special care in handling or storage;

(i) The statement "keep out of the reach of children," or its practical equivalent. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-3. Prominence of required information. All statements required in these regulations to appear on the labels of household products shall be located prominently thereon and shall be printed in English in legible type in contrast by typography, layout, or color with other printed material on the label. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-4. Small package exemptions. On labels of packages where the size of the container makes it impractical to include all of the subject matter required by 28-27-2, the statement of precautionary measures describing action to be followed or avoided may be abbreviated and the instructions for handling and storage of package may be deleted. In other cases, including substances presenting only minor hazards, application to vary from the prescribed labeling requirements in 28-27-2 shall be made to the Kansas state board of health. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-5. Practical equivalent of wording permitted. Use of language on labels which is the practical equivalent of that suggested in 28-27-2 shall constitute compliance with these regulations, except that no words shall be regarded as the practical equivalent of the word "POISON" or "POISONOUS." (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-6 to 28-27-9. Reserved.

B. PAINTS, VARNISHES AND SIMILAR PRODUCTS

28-27-10. Articles containing toxic metal compounds. Paints, varnishes and similar products containing not more than one percent of lead as metal (Pb), and not containing compounds of antimony, arsenic, cadmium, mercury, selenium, or barium (when soluble by stirring for 10 minutes with five percent hydrochloric acid at room temperature) introduced as such in the formulation of these products, and flashing below 150° F., shall bear the following cautionary labeling printed in type of sufficient size and prominence and in such contrast as to be easily readable under the normal conditions of sale and use:

(a) For products with a flash point above 80° F., and which are toxic by inhalation, ingestion or skin contact:

CAUTION! COMBUSTIBLE

Keep away from heat and open flame. Use with adequate ventilation. Avoid prolonged or repeated contact with skin. Avoid prolonged breathing of vapor or spray mist. Keep container closed when not in use.

(b) For products with a flash point above 20° F. and not higher than 80° F., and which are toxic by inhalation, ingestion or skin contact:

WARNING! FLAMMABLE

Keep away from heat, sparks, and open flame. Use with adequate ventilation. Avoid prolonged or repeated contact with

skin. Avoid prolonged breathing of vapor or spray mist. Keep container closed when not in use.

(c) For products with flash point of 20° F. or lower, and which are toxic by inhalation, ingestion or skin contact:

DANGER! EXTREMELY FLAMMABLE

Keep away from heat, sparks, and open flame. Use with adequate ventilation. Avoid prolonged or repeated contact with skin. Avoid prolonged breathing of vapor or spray mist. Keep container closed when not in use.

(Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-11. Articles marked "do not take internally." The words "do not take internally" may be omitted from the labeling of articles described in 28-27-10 except in the case of clear liquids, such as thinners. Regardless of flash point, these clear liquids shall bear appropriate labeling as indicated in 28-27-10 plus the warning "do not take internally." (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-12. Flash point, definition. "Flash point" shall mean, for the purposes of these regulations, the flash point as determined by the Tagliabue open cup method, as specified in the American society for testing materials method D1310-55T. The percentage of lead shall be determined as lead metal (Pb) based on the total solids of the product. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-13. Odorless solvents. Products described in 28-27-10 which contain "odorless" solvents shall be labeled with appropriate cautionary statements specified in 28-27-10, but the words "use with adequate ventilation" shall be in type two points larger than the type used for the rest of the cautionary labeling. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-14. Articles containing toxic metal compounds. Paints, varnishes, and similar products containing more than one percent of lead as metal (Pb) in compound, or containing a compound of antimony, arsenic, cadmium, mercury, selenium or barium (when soluble by stirring for 10 minutes with five percent hydrochloric acid at room temperature) introduced as such in the formulation of the products, and a solvent flashing below 150° F., shall bear the following cautionary labeling printed in type of sufficient size and prominence and in such contrast as to be easily readable under the normal conditions of sale and use.

(a) For products with flash point above 80° F.:

CAUTION! COMBUSTIBLE

Keep Away From Heat and Open Flame
CONTAINS LEAD OR OTHER COMPOUNDS HARMFUL IF EATEN

Do not apply to toys, furniture or interior surfaces which might be chewed by children. Use with adequate ventilation. Avoid breathing vapor or spray mist. Avoid prolonged contact with skin. Wash thoroughly after handling and before eating or smoking. Keep container closed when not in use.

(b) For products with flash point above 20° F. and not higher than 80° F.:

WARNING! FLAMMABLE

Keep Away From Heat, Sparks, and Open Flame
CONTAINS LEAD OR OTHER COMPOUNDS HARMFUL IF EATEN

Do not apply to toys, furniture or interior surfaces which might be chewed by children. Use with adequate ventilation. Avoid breathing vapor or spray mist. Avoid prolonged contact with skin. Wash thoroughly after handling and before eating or smoking. Keep container closed when not in use.

(c) For products with flash point below 20° F.:

DANGER! EXTREMELY FLAMMABLE

Keep Away From Heat, Sparks, and Open Flame
CONTAINS LEAD OR OTHER COMPOUNDS HARMFUL IF EATEN

Do not apply to toys, furniture or interior surfaces which might be chewed by children. Use with adequate ventilation. Avoid breathing vapor or spray mist. Avoid prolonged contact with skin. Wash thoroughly after handling and before eating or smoking. Keep container closed when not in use.

(Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-15. Articles containing lead; labeling. When more than one percent of lead is the only harmful compound used in a product described in 28-27-14 the words "contains lead or other compounds harmful if eaten" may be changed to "contains more than one percent lead (Pb) harmful if eaten." (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-16. Articles containing harmful solvents. Paints, varnishes, paint removers and similar products, not described in 28-27-14 containing significant amounts of materials or solvents which may be harmful shall bear cautionary statements warning the user of hazards existing in their use. Manufacturers shall be guided in the labeling of this class of products by the principles set forth in manufacturing chemists association manual L-1 warning labels applying to the specific hazardous chemicals involved. (Authorized by

K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-17 to 28-27-19. Reserved.

C. TOYS

28-27-20. Toys bearing toxic paints prohibited. The sale of any toy is prohibited if it is coated with paints and lacquers containing compounds of lead of which the lead content (calculated as Pb), is in excess of one percent of the total weight of the contained solids (including pigments and drier), or soluble compounds of antimony, arsenic, cadmium, mercury, selenium or barium, introduced as such. Compounds are considered soluble if quantities in excess of 0.1 percent are dissolved by five percent hydrochloric acid after stirring for 10 minutes at room temperature. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-21. Toys made of toxic plastics prohibited. The sale of any toy made in whole or in part of a plastic containing leachable toxic constituents if prohibited. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-22. Toys filled with toxic fluids prohibited. The sale of any toy filled with any toxic fluid which might be injurious upon breakage or leakage is prohibited. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-23. Bubble-forming materials to be nontoxic. Materials intended for blowing bubbles, whether aqueous or plastic, shall be composed only of materials which are nontoxic by ingestion, inhalation, absorption through the skin or through the eyes. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-24. Fuels for toys and models, labeling. Fuels for use in toys or models shall bear all the labeling information required under 28-27-2. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-25. Pigments, solvents or bodies in certain toys to be nontoxic. Pigments, solvents or bodies used in such toys as crayons, chalks, modeling clays, doughs, etc., shall be nontoxic. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

28-27-26 to 28-27-29. Reserved.

D. INSECTICIDE VAPORIZING DEVICES

28-27-30. Devices for vaporizing chlorinated hydrocarbons prohibited. No person, corporate or natural, shall advertise or label any device, intended for household use which is designed and intended to vaporize by heat any chlorinated hydrocarbon insecticide, in such a manner as to suggest, imply, or recommend that the device is to be used while any person occupies the premises where such use takes place, nor shall any person advertise or label such device so as to suggest, imply, or recommend that it be used in living quarters for any period in excess of eight (8) hours or more frequently than at fourteen (14) day intervals.

The term "label" as used in this regulation refers to any written, printed or graphic matter appearing on or accompanying the retail wrapper or package of the devices described herein. The term "advertise" refers to the making of any representation, disseminated in any manner or by any means other than by a label, for the purpose of inducing, or which is likely to induce directly or indirectly, the purchase of insecticide vaporizing devices.

The sale, offering for sale or holding for sale of any vaporizing devices which are advertised or labeled in violation of this regulation is prohibited: *Provided, however,* That no person shall be held in violation for advertising unless he shall in some way have disseminated or aided in dissemination of such advertising. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

E. CYANIDE METAL POLISHES; PROHIBITED

28-27-31. Metal polishes containing cyanides prohibited. The sale, offering for sale, or holding for sale in Kansas of any metal polish intended for household use which contains any cyanides or substances which may react to produce the cyanide radical (CN) is prohibited. (Authorized by K.S.A. 1965 Supp. 65-2703; effective Jan. 1, 1966.)

Article 28.—HYPNOTIC, SOMNIFACIENT OR STIMULATING DRUGS

28-28-1 to 28-28-2. (Authorized by K.S.A. 65-2606; effective Jan. 1, 1967; revoked May 10, 1996.)